DPS

DEPARTMENT OF PHARMACEUTICAL SERVICES
MINISTRY OF HEALTH
BANDAR SERI BEGAWAN
BRUNEI DARUSSALAM

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Rujukan Kami : (08) PRS/ADMIN/2021
Our Reference

29 Rabiulakhir 1443
4 December 2021

Dear Product Licence Holders and Importers,

IMPORTATION AND SALE OF ANGIOTENSIN-II RECEPTOR BLOCKERS (ARBs) IN BRUNEI DARUSSALAM

There have been recent reports on the presence of azido impurity, 5-[4'-[(5-(azidomethyl)-2-butyl-4-chloro-1H-imidazol-1-yl)methyl]-[1,1'-biphenyl]2-yl]-1H-tetrazole in certain Angiotensin-II Receptor Blockers (ARBs) through our pharmacovigilance activities. The presence of internationally unacceptable levels of these impurities which are potentially mutagenic has resulted in voluntary recalls by the manufacturers of the affected products.

As a precautionary measure, The Brunei Darussalam Medicines Control Authority (BDMCA) in its 39th Meeting held on 24th November 2021 has reviewed and updated the requirements for the importation and sale of ARBs. All product licence holders and importers are required to provide the following documents for every consignment coming into Brunei Darussalam:

i) The batch numbers and quantity of the finished products that are planned to be imported into Brunei Darussalam including where it is supplied to
ii) Certificate of Analysis of Finished Product corresponding to the batch imported into Brunei Darussalam
iii) Certificate of Analysis of the Active Pharmaceutical Ingredient used to manufacture the finished product corresponding to the batch imported into Brunei Darussalam
iv) Information on the level of *N*-nitrosamine impurities, including but not limited to N-nitrosodimethylamine (NDMA), N-nitrosodiethylamine (NDEA) and N-nitroso-N-methyl-4-aminobutyric acid (NMBA) of the specific batch imported into Brunei Darussalam
v) Information on the level of Azido impurity of the specific batch imported into Brunei Darussalam
vi) Declaration letter from the manufacturer of the finished product indicating impurity is not detected / below acceptable levels in cases where impurity results are unavailable for the specific batch imported into Brunei Darussalam.

This letter supersedes the letter on Importation and Sale of Angiotensin-II Receptor Blockers (ARBs) in Brunei Darussalam, ref: (133) DPS/ADMIN/2018 dated 13th March 2019.

Thank you for your kind attention and cooperation in the matter.

Yours sincerely,

(Dyg Hjh Zanatul 'Aini Hj Zainin)
Acting Director of Pharmaceutical Services
For Chair of BDMCA