DPS

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

جابتن ڤرخدمتن فرماسي

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Rujukan Kami :
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Dear Product Licence Holders and Importers,

IMPORTATION AND SALE OF RANITIDINE PRODUCTS IN BRUNEI DARUSSALAM

Recently, there have been findings in the detection of N-nitrosodimethylamine (NDMA), a probable human carcinogen in several ranitidine products through our pharmacovigilance activities. The presence of NDMA has resulted in voluntary recalls by the manufacturers of the affected products.

Following the recent BDMCA Meeting held on 9th October 2019, it was decided for all ranitidine products (that were not affected by the recent recall) to be placed under close vigilance as a precautionary measure. In our continuous effort to monitor the importation and sale of ranitidine products, 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
ii) Certificate of Analysis of Finished Product corresponding to the batch imported into Brunei
iii) Certificate of Analysis of the Active Pharmaceutical Ingredient used to manufacture the finished product corresponding to the batch imported into Brunei
iv) Information on impurity level of NDMA of the specific batch imported into Brunei.

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

Yours sincerely,

(WEE SHYUE LIANG)
Acting Director of Pharmaceutical Services
For Chair of BDMCA