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

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Our Reference

3 Muharram 1443
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Dear Product Licence Holders and Importers,

IMPORTATION AND SALE OF AMITRIPTYLINE PRODUCTS IN BRUNEI DARUSSALAM

Recently there have been findings in the detection of N-nitrosodimethylamine (NDMA), a probable human carcinogen in several Amitriptyline products through our pharmacovigilance activities. The presence of internationally unacceptable levels of NDMA has resulted in recalls of the affected Amitriptyline products by the regulatory authority in Canada.

The Brunei Darussalam Medicines Control Authority (BDMCA) in its 38th Meeting held on 12th July 2021 has determined for all Amitriptyline products in Brunei to be placed under close vigilance. In our continuous effort to monitor the importation and sale of Amitriptyline 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 including where it is supplied to
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,

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