

DPS

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



جايتن فر خدمتن فر ماسي

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Rujukan Kami : (09) PRS/ADMIN/2021
Our Reference

29 Rabiulakhir 1443
4 December 2021

Dear Product Licence Holders and Importers,

IMPORTATION AND SALE OF VARENICLINE PRODUCTS IN BRUNEI DARUSSALAM

There have been recent findings of internationally unacceptable levels of a nitrosamine impurity, N-nitroso-varenicline (NNV), a probable human carcinogen in several Varenicline products through our pharmacovigilance activities. The presence of NNV in amounts beyond accepted levels has resulted in recalls of the affected Varenicline products in Brunei Darussalam as well as by regulatory authorities in other countries.

The Brunei Darussalam Medicines Control Authority (BDMCA) in its 39th Meeting held on 24th November 2021 has determined for all Varenicline products in Brunei Darussalam to be placed under close vigilance. In our continuous effort to monitor the importation and sale of Varenicline 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 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 impurity level of NNV of the specific batch imported into Brunei Darussalam.
- v) Declaration letter from the manufacturer of the finished product indicating impurity is not detected / below acceptable levels in cases where the impurity result is unavailable for the specific batch imported into Brunei Darussalam.

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