

# DPS

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



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Rujukan Kami : (01) PRS/ADMIN/2021  
*Our Reference*

3 Muharram 1443  
12 August 2021

Dear Product Licence Holders and Importers,

**DIRECTIVE FOR PROMETHAZINE CONTAINING PRODUCTS IN BRUNEI DARUSSALAM: UPDATE ON PRODUCT LABELLING / PACKAGE INSERT ON ITS USE IN CHILDREN UNDER 6 YEARS OF AGE FOR THE TREATMENT OF COUGH AND COLD**

The Brunei Darussalam Medicines Control Authority in its 38<sup>th</sup> Meeting held on 12<sup>th</sup> July 2021 has determined for information on all promethazine containing products registered and marketed in Brunei Darussalam to be updated, particularly with regards to its use in children under 6 years of age for the treatment of cough and cold. This update was based on information from regulatory authorities in Australia, UK and USA.

2. Therefore, all product licence holders and importers are required to update the product labelling / package insert to remove the indication for the treatment of cough and cold in children under 6 years of age on all products containing promethazine. Promethazine may however be used in children under 6 years of age for indications other than cough and cold.
3. The implementation date on the requirement is as follows:
  - i) New applications and applications that are still in process of registration: **1 October 2021**
  - ii) Registered products: **1 April 2022** (grace period of 6 months from the implementation date). Update on product labelling / package insert for **registered** products is required to be submitted as variation application prior to the implementation date.

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