

DPS

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



جايتن فر خدمتن فر ماسي

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Rujukan Kami : (12) PRS/ADMIN/2021
Our Reference

6 Jamadilawal 1443
11 December 2021

Dear Product Licence Holders and Importers,

**DIRECTIVE FOR PHOLCODINE CONTAINING PRODUCTS IN BRUNEI DARUSSALAM:
UPDATE ON PRODUCT LABELLING / PACKAGE INSERT ON ITS USE IN CHILDREN**

The Brunei Darussalam Medicines Control Authority in its 39th Meeting held on 24th November 2021 has determined for information on all pholcodine containing products registered and marketed in Brunei Darussalam to be updated, particularly with regards to its use in children. This update was based on findings of the latest prescribing guidance as well as information from regulatory authorities in Australia and UK.

2. Therefore, all product licence holders and importers are required to update the product labelling / package insert to remove the indication in children under 6 years of age on all products containing pholcodine. The following information must also be included:

- Do not use in children under 6 years of age
- Use with caution upon the advice of the doctor / pharmacist in children 6 to 12 years of age
- Do not use for more than 5 days
- If cough persists, please consult your doctor

3. The implementation date on the requirement is as follows:

i) New applications and applications which are still in process of registration: **1 January 2022**

ii) Registered products: **1 July 2022**

4. 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