

# DPS

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



## جايتن فر خدمتن فر ماسي

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Rujukan Kami : (10) PRS/ADMIN/2021  
Our Reference

6 Jamadilawal 1443  
11 December 2021

Dear Product Licence Holders and Importers,

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

The Brunei Darussalam Medicines Control Authority in its 39<sup>th</sup> Meeting held on 24<sup>th</sup> November 2021 has reviewed and updated the information required for all dextromethorphan containing products registered and marketed in Brunei Darussalam. This update was based on findings of the latest prescribing guidance as well as information from regulatory authorities in Australia, UK and USA.

2. This directive now supersedes the Directive for Dextromethorphan containing products in Brunei Darussalam: Update on Product Labelling / Package Insert on its Use in Children under 12 years of age, ref: (02) PRS / ADMIN / 2021 dated 12<sup>th</sup> August 2021.
3. All product licence holders and importers are therefore required to update the product labelling / package insert to remove the indication in children under 6 years of age on all products containing dextromethorphan. 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: **immediate effect commencing 11 December 2021**
  - ii) Registered products: **11 June 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,

A handwritten signature in blue ink, appearing to read 'Zainin'.

**(Dyg Hj Zanatul 'Aini Hj Zainin)**

Acting Director of Pharmaceutical Services  
For Chair of BDMCA