GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH
MINISTRY OF HEALTH AND FAMILY WELFARE
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
AUSHADH BHABAN
MOHAKHALI, DHAKA, BANGLADESH
www.dgda.gov.bd

Ref. WHO TRS 993, 2015 ANNEX-4 Date: 01/04/2020

Guidelines on Procedures and Data Requirements for Changes to Approved Vaccines

DGDA, as a competent medicine regulatory authority gives marketing authorization of a new pharmaceutical product for the purpose of marketing or distribution after evaluation of its safety, efficacy and quality.

For any post market changes MA holder should follow the relevant Procedures and data requirements for changes to approved vaccines as per this guideline

To approve post market changes properly and effectively guidelines are needed. In this purpose WHO Guidelines on procedures and data requirements for changes to approved vaccines products is very extensive guidelines which also covered all the aspect and issues of post market variation.

So here this is to certify that WHO Guidelines on Procedures and data requirements for changes to approved vaccines WHO TRS 993, 2015, Annex-4 is adopted for the purpose of variation of marketing authorization in DGDA from the date given below and valid up to next office order.

01/04/2020

Major General Md Mahbubur Rahman
Director General
Directorate General of Drug Administration
&
Licensing Authority (Drugs)