GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH
MINISTRY OF HEALTH & FAMILY WELFARE
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
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Ref. WHO TRS 981, 2013 ANNEX-3

Date: 01/04/2018

Guidelines on variation

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.

After a product has been authorized for marketing, the MA Holder often make changes/ variation which are either minor or major.

To address those variation properly and effectively guidelines are needed. In these purpose WHO Guidelines on variation to prequalified products is very extensive guidelines which also covered all the aspect and issues of variation of marketing authorization.

So here this is to certify that WHO Guidelines on variation to prequalified products (page: 93;94;95;96-154) is adopted for the purpose of variation of marketing authorization in DGDA from the date given below and valid up to next office order.

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