Government of the People's Republic of Bangladesh
Directorate General of Drug Administration
Ministry of Health and Family Welfare
Mohakhali, Dhaka-1212.
www.dgda.gov.bd

DA/MA-341/06/ 2924 Date: 23.07.2019

To
M/s Beacon Pharmaceuticals Limited
Kathali, Bhaluka, Mymensingh

Subject: Certificate for Marketing Authorization of Drug/Biologicals/Vaccines/Medicinal Devices.

In response to application, reference number **BPL/DA/19/124** for marketing authorization of the following product, DGDA hereby inform you that the evaluation of the application has been completed.

Trade name	: Bical
Generic Name(s)	: Bicalutamide INN
Strength(s) per dosage units	: 50mg
Dosage form	: Tablet
Manufacturing Site	: Beacon Pharmaceuticals Limited, Kathali, Bhaluka, Mymensingh, Bangladesh
Shelf Life	: 02 years
Storage Condition	: Below 30^0 C
Name of marketing Authorization holder	: Beacon Pharmaceuticals Limited, Kathali, Bhaluka, Mymensingh, Bangladesh

The approval of marketing authorization has been given subject to the conditions in this certificate and it's attachments. This certificate and its attachments constitute the marketing authorization. The details of this authorization are as follows.

Marketing Authorization Number : MA No. 341-247-010
Date of Marketing Authorization : 22.07.2019
Expiry date of Marketing Authorization: 13-08-2024

Digitally signed by Ostapciuc Alexandr
Date: 2021.12.14 16:40:57 EET
Reason: MoldSign Signature
Location: Moldova

MINISTRY OF HEALTH & FAMILY WELFARE ★ DIRECTORATE GENERAL OF DRUG ADMINISTRATION ★ GOVT. OF THE PEOPLE'S REPUBLIC OF BANGLADESH ★ DHAKA

Major General Md Mahbubur Rahman
Director General
Directorate General of Drug Administration
&
Licensing Authority (Drugs)
Govt. of the People's Republic of Bangladesh

22 JUL 2019

Conditions which apply to this approval are as follows:

1. The product(s) must conform with all the details provided in your application and as modified in subsequent correspondence.
2. No changes may be made to the product without prior approval of the Licensing Authority (Drugs).
3. The approved sites of manufacture stated in Attachment-1 (Annexure-I/Annexure-II approved formulation).
4. The Approved shelf life stated above and in the Attachment-2 (Stability Study Report), may be changed having the prior approval of Licensing Authority.
5. The only Product Information (PI) that may be supplied with or for this product must be the PI that is approved. Attachment-3 is a copy of the approved PI (Product Information).
6. Text/design of packaging materials can not be changed without approval. Approved packaging materials should be attached (Attachment-4).
7. The Product Information (PI) may not be altered without prior approval of Licensing Authority, except for safety updates that further restrict use of the product. Any such safety-related changes must be notified to the Licensing Authority within five days of making the changes.
8. The approved product price has to be printed on the packaging materials clearly. Over stamping/ price tempering/price sticker on printed price is not allowed Price Certificate should be attached (Attachment-5).
9. Pharmacovigilance of this product has to be conducted on regular basis & report has to be submitted to DGDA if any adverse effect is not iddentified or received nil report has to be submitted to DGDA.
10. MA holder has to conduct Post Marketing Surveillance (PMS) of the product and report to DGDA 03 (three) monthly.