### No.F.10-11/2022-DD (Health & OTC) (112-M)

AUTHORING BEGRE

Government of Pakistan Ministry of National Health Services, Regulations & Coordination DRUG REGULATORY AUTHORITY OF PAKISTAN TF Complex, Sector G-9/4, Islamabad

#### **"SAY NO TO CORRUPTION"**

Islamabad, the 10<sup>th</sup> February, 2023

M/s W. Welkins Pharma Co., Plot No. C 31-32, Small Industrial Estate, Abbottabad, Khyber Pakhtunkhwa.

Subject:

# <u>REVOCATION / CANCELLATION OF FORM-6 (PROVISIONAL</u> <u>CERTIFICATE FOR ENLISTMENT AS MANUFACTURER/IMPORTER) &</u> <u>FORM-7 (PROVISIONAL CERTIFICATE FOR ENLISTMENT OF PRODUCTS).</u>

I am directed to refer the subject cited above and to communicate the decision of Enlistment Evaluation Committee (EEC) taken in its 112<sup>th</sup> Meeting held on 03<sup>rd</sup> November, 2022:

2. That the Additional Director, DRAP, Peshawar, forwarded the report of M/s W. Welkins Pharma Co., located at Plot No. C 31-32, Small Industrial Estate, Abbottabad, Khyber Pakhtunkhwa (E. No.00151), vide letter No. F.3-20/2018-Welkins-DRAP-(P)-4962, dated 30-12-2021, with following concluding remarks;

## "Concluding Remarks and Recommendations

The firm is non-compliant to manufacturing requirements of H&OTC Products and operating without any technical person or QC testing, posing risk of sub-standard H&OTC Products. The firm is directed to stop production immediately. Stocks/Packing materials ordered not to dispose of on Form-I. Products manufactured without Form-7 are seized on F-1 for further proceedings. Form-6 of the firm may be cancelled/suspended as per H&OTC rules."

3. That the said case was considered by the EEC, in its 102<sup>nd</sup> meeting, held on 13<sup>th</sup> January, 2022 and the Committee decided as under;

"Decision: After detailed discussion and deliberation on the matter and under the light of the recommendations of the inspector, forwarded vide inspection report No. F.3-20/2018-Welkins-DRAP-(P)-4962, dated 30-12-2021, wherein it is recommended to cancel the Form-6 of the firm, due to the reason that the firm is non-compliant to manufacturing requirements of H&OTC Products and operating without any technical person or QC testing, posing risk of sub-standard H&OTC Products, the EEC directed the firm to immediately stop the production and to show in writing, within 07 days of communication of this decision, that why not the provisional enlistment of the firm, may be revoked due to the violations as mentioned above."

4. That in compliance to the above decision of the EEC, a show cause notice was issued to the firm vide No.F.10-1/2022-DD-(H&OTC)-(M-102), dated 07-02-2022. However, the firm has not submitted any

Page 1 of 2

Most Immediate Through UMS response. Show cause notice and Personal hearing notices were issued and are not returned back undelivered.

## 5. Proceedings and Decision of the 112th meeting of EEC:-

As the firm has not submitted any response to show cause and did not appear before the EEC on stipulated date and time, the EEC after threadbare deliberation and consideration of the case in detail unanimously is of the opinion that the firm has nothing to present in his defense. Accordingly, the EEC decided to revoke the Provisional Enlistment of M/s W. Welkins Pharma Co., located at Plot No. C 31-32, Small Industrial Estate, Al bottabad, Khyber Pakhtunkhwa (E. No.00151), with immediate effect in the best interest of public health and safety. The firm is further directed to surrender Certificates of enlistment (Form-6 and all Form-7 issued in favor of M/s W. Welkins Pharma Co.) to the Authority within 7 days of issuance of this decision.

6. Therefore, Provisional Enlistment N .. 00151 issued in the nume of M/s W. Welkins Pharma Co., located at Plot No. C 31.32, Small Industrial Estate, A bbottabad, Khyber Pakhtunkhwa stands revoked with immediate effect. You are therefore ordered to surrender Certificates of enlistment including Form-6 and all Form-7 issued in favor of M/s W. Welkins Pharma Co., located at Hot No. C 31-32, Small Industrial Estate, Abbottabad, Khyber Pakhunkhwa to the Authority within 7 days of issuance of this decision.

7. You are therefore directed to comply with the dccision of Er listment Evaluation Committee (EEC) in its letter and spirit.

8. If you are aggrieved with the decision of EEC, you may prefer an appeal before the Appellate Board under prescribed rules and procedure within stipulated time.

212023

(Farman Ali Bozdar) Dep ity Director/E esignated Officer, Division of Health and OTC, Drug Regulatory Authority of Pakistan, Islamabad.

Copy to:-

- i. Chairman EEC/Director (H&OTC), DRAP, Isl: mabad.
- ii. The Director, QA&LT, DRAP, Islar labad for information and necessar / action, Please.
- Viii. The Director, MIS, DRAP, Islamab id for up loading this letter on official website of DRAP in larger public interest.
  - iv. The Additional Director, DRAP, Pethawar for information and necessary action, Please.
  - v. The Chief Drug Controller, Pur jab/: indh/KPK Baluchistan/AJK/GB/Sr. inspector of Drugs, ICT - for information and necessary action.
  - vi. Area Federal Inspector of Drugs, DI AP, Pesha war for information and necessary action, please.
- vii. Office Copy.
- viii. Company file.