

No. F. 10-02/2016-DDC (Health & OTC)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
DRUG REGULATORY AUTHORITY OF PAKISTAN

Islamabad, the 1st March, 2016

MINUTES OF THE 8TH MEETING OF ENLISTMENT EVALUATION COMMITTEE FOR ALTERNATIVE MEDICINES AND HEALTH PRODUCTS

8th Meeting of the Enlistment Evaluation Committee (EEC), constituted under Rules 7 of the Alternative Medicines and Health Products (Enlistment) Rules, 2014, was held in the office of the Chairman of the Committee on 1st March, 2016. Meeting of Committee was attended by the following:-

S. #.	Name & Designation	Position in the Committee
1.	Dr. Noor Muhammad Shah, Director Health & OTC	Ex-Officio Chairman
2.	Abdul Sattar Sohrani, Deputy Drug Controller Health & OTC	Ex-Officio Member / Secretary
3.	Homeopathic Dr. Muhammad Tariq Khan, Assistant Professor, Department College of Pharmacy, Margalla Institute of Health Sciences, Rawalpindi.	Expert Member
4.	Hafiz Muhammad Asif, Assistant Professor Faculty of Health and medical Sciences Department of Eastern Medicines and Surgery, University of Poonch (Rawala Kot), AJ&K.	Expert Member
5.	Dr. Lajbar Khan, Ex-Chief Scientific Officer, Medicinal Botanic Centre, PCSIR Laboratories Complex, Peshawar.	Expert Member
6.	Dr. Farnaz Malik, Chief, DC & TMD, NIH	Ex-Officio Member -Not Present-
7.	Dr. Amjad Ali, Chief, Nutrition Division, NIH	Ex-Officio Member

ITEM NO. 1. Meeting started with recitation of the Holy Quran and Darud on the Prophet (PBUH). Secretary of the Committee presented agenda of the meeting and following decisions were made by the Committee.

ITEM NO. 2. GRANT OF ENLISTMENT CERTIFICATE TO THE MANUFACTURERS

Enlistment Evaluation Committee (EEC) examined and discussed the record / panel inspection reports of the following firms on the basis of recommendations of the panel of inspectors for the grant of enlistment certificates for manufacturing authorization.

S. No.	Name and address of the Manufacturer	Name of approved Sections
1.	M/s. W. Walkins Pharma Co. , Plot No. C 31-32, Small Industrial Estate, Abbottabad.	1. Tablet 2. Capsule 3. Oral liquid (Syrup) 4. Ointment/ Cream 5. Sachet
2.	M/s ICI Pakistan Ltd. , ICI House, 5 West Wharf, Karachi-74000.	1. Oral liquid (Syrup) 2. Tablet 3. Capsule (softgel) 4. Sachet
3.	M/s Herbtech Laboratories , CI-70, Sector 6- B, North Karachi Industrial Area, Karachi.	1. Sachet 2. Tablet 3. Capsule 4. Dry Powder 5. Oral liquid (syrup & drops) 6. Cream/ Ointment
4.	M/s Gluck Laboratories (Pvt.) Ltd. , Saggyan Kalanwar Near Rehman City Phase-IV, off Saggyan Bridge, Lahore.	1. Oral Liquid
5.	M/s Wilshire Laboratory (Pvt.) Ltd. , Plot No. 5-Farooq Industrial Estate, 20-KM, Ferozpur Road, Lahore.	1. Tablet 2. Capsule 3. Oral liquid (syrup & drops) 4. Semisolid (ointment/ cream/ gel) 5. Dry powder sachet/ tin 6. Liquid sachet 7. Eye/ ear & nasal drops 8. Sterilization facility
6.	M/s Gentle Care Corporation , Said Anwar Street Rang Muhallah Mingora, Swat.	1. Tooth Paste 2. Mouthwash
7.	M/s Medinoon Research Laboratories , 28- Km, Soay Assal Stop, Ferozpur Road, Lahore.	1. Tablet 2. Capsule 3. Powder
8.	M/s Reign Nutro Pharma (Pvt.) Ltd. , Plot No. L-1-C/1, Federal "B" Industrial Area, Shaheed Rashid Minhas Road, Karachi.	1. Sachet/ dry powder 2. Tablet 3. Capsule 4. Oral liquid (syrup & drops) 5. Cream/ Ointment

9.	M/s Curative Pharmaceuticals (Pct) Ltd., (Nutraceuticals Division) Plot No. 34, St. No. 5, National Industrial Zone (RCCI), Rawat, Rawalpindi.	1. Sachet 2. Oral liquid (syrup)
10.	M/s Cynosure Pvt. Ltd. , Plot No. 21-A, Tawakkal Town, Old Shuja Abad Road, Multan.	1. Tablet 2. Oral liquid 3. Sachet 4. Capsule 5. Cream/ Ointment
11.	M/s Cidex Laboratories , 84-B S.I.E Kohat Road, Peshawar.	1. Oral liquid 2. Tablet 3. Capsule 4. Sachet 5. Topical semisolid (cream/ ointment/ gel)

2. **INSPECTION REPORT NOT RECOMMENDED BY THE PANEL:-**

1.	M/s Arshzik Nutraceuticals , 23-Km, Near Al-Ghani CNG, G.T. Road, Rawat, Rawalpindi. Section: - 1. Sachet (Veterinary) 2. Syrup (Veterinary)	18-02-2016	01. Mr. Khalid Mahmood, FID-II, DRAP, Islamabad. 02. Mr. Jawad, PDI, Rawalpindi.	Not Good	Committee rejected the application due to the reasons given by the Panel in the Inspection Report.
----	---	------------	---	----------	--

Decision

- EEC rejected the application because panel did not recommend the facility due to the reasons given in the inspection report presented by the Secretary (EEC).
- Principal decision:** Committee decided the applicants whose applications have been rejected on the basis of non recommendation by the panel may apply a fresh after fulfillment of legal requirements and his case will be taken on priority basis.

ITEM NO. 3. GRANT OF ENLISTMENT CERTIFICATES TO IMPORTERS AS AN AGENT OF PRINCIPLE MANUFACTURER.

The Enlistment Evaluation Committee considered the applications/ record and evaluated the case of enlistment of the following firms and granted approval for Enlistment Certificates on Form-6

(A-1) Application for Enlistment as agent of abroad Principal Manufacturer meeting the prescribed criteria

1. **M/s B.M Biotech**, 69 A, Guldasht Town, Zarar Shaheed Road, Lahore Cantt.
(Agent of **M/s Quest Vitamins Middle East FZE**, Plot No. S20708A, Jebel Ali Free Zone, P.O. Box 17836, **DUBAI, UAE**)
2. **M/s UUAMA International Group**, Office No. 8, 1st Floor Safdar Mention, Fazal-e-Haq Road, Blue Area, Islamabad.
(Agent of **M/s Zhengzhou Biocaro Pharmaceutical & Health-care Products Co., Ltd.** No. 5, Hehuan Street, High Tech Development Area, Zhengzhou, Henan, **CHINA**)
3. **M/s Saviour Pharma**, 233, H4 Wapda Town, Lahore.
(Agent of **M/s Shandong Yuwang Pharmaceutical Co., Ltd.** The North of Tongqu Road, Yucheng City, Shandong **CHINA**)
4. **M/s Tarobina Corporation**, 226-Ahmed Block New Garden Town, Lahore.
(Agent of **M/s Nutristar International S.A.**, 2 avenue des Arpents-BP 80314 Osny 95526 Cergy-Pontoise CEDEX, **FRANCE**)(Veterinary use)
5. **M/s APEX Pharmaceutical (Pvt.) Limited**, D-21, A/1, S.I.T.E Super Highway, Karachi.
(Agent of **M/s WALMARK, A.S.**, Ordřichovice 44, 739 61 Trinec, **Czech Republic**)
6. **M/s Eli Lilly Pakistan (Pvt.) Limited**, 5A, 5th Office Floor (10th Building Floor), Al-Tijara Center, 32-1-A, Block 6, PECHS, Main Shahrah-e-Faisal, Karachi 75400.
(Agent of **M/s Lusomedicamenta, Sociedade Tecnica Farmaceutica, SA**, Estrada Consiglieri Pedroso, 69-B, Queluz de Baixo 2730-055 Barcarena, **PORTUGAL**)
7. **M/s Faster Pharmaceuticals**, Faster House No. 4, Madina Town, Near Islamia College, Jhang Road, Toba Tek Singh.
(Agent of **M/s Uramel International**, ALPHATECH – ZI du Grand Plessis – 22940 Plaintel **FRANCE**)
8. **M/s Z/Y Corporation**, DZHP, Plot No. 18, Sector 14, Korangi Industrial Area, Karachi.
(Agent of **M/s Pfluger GmbH Co. KG**, Röntgenstraße 4 33378 Rheda Wiedenbrück, **GERMANY**)(Homoeopathy)
9. **M/s Mind Fire Media**, 1st Floor, P/130, Kohinoor City, Jarranwala Road, Faisalabad.
(Agent of **M/s SIRIO Pharma. Co. Ltd.**, No. 83, Taishan Road. Shantou, Guangdong, **CHINA 515041**)

10. **M/s Penzi Business Organization**, 326, Al-Sadiq, D.M.C.H.S, Hyder Ali Road, Karachi.
(Agent of **M/s Herbamed AG**, Austrasse 12, CH-9055 Bühler, **SWITZERLAND**)
(Homoeopathy)
11. **M/s MTA Traders**, 398-B1, Johar Town, Lahore.
(Agent of **M/s Prime Performance Nutrition**, 20573 Country Road 297, Cosby Missouri 64436, **USA**)

Decision

The Enlistment Evaluation Committee considered the applications/ record and evaluated the application for enlistment of the above firms and granted approval for Enlistment Certificates on Form-6

(A-2) Application for Enlistment as agent of abroad Principal Manufacturer meeting the prescribed criteria

1. **M/s Kaap Pharmaceuticals (Pvt.) Ltd.**, 18-KM, Freozepur Road, Lahore.
(Agent of **M/s SIRIO Pharma. Co. Ltd.**, No. 83, Taishan Road. Shantou, Guangdong, **CHINA 515041**)

Decision:

The Enlistment Evaluation Committee considered the application/ record and evaluated the application for enlistment of the firm and decided to defer the application for further evaluation because firm has applied for the product VitaminD3 200000IU which does not come under the definition of Food Supplements.

2. **M/s Pharma Five (Pvt.) Ltd.**, C-157, K.D.A Scheme 1, Karachi.
(Agent of **M/s Synbio Tech Inc.**, No. 66, Beiling 6th Rd, Luzhu District, Kaohsiung City 821, **TAIWAN (R.O.C)**)

Decision:

The Enlistment Evaluation Committee considered the application/ record and evaluated the application for enlistment of the firm and decided to defer the application for further evaluation because applicant has submitted application without attestation of import documents by the Embassy of Pakistan or its Consulates. The attestation by the Foreign Ministry camp office is not admissible under the rules.

(B) The Firms having agency agreement / attestation of manufacturing authorization of the Principal Manufacturer not attested

1. **M/s Genetics Healthcare, 537-A, Sundar Industrial Estate, Lahore.**
(Agent of **M/s Gnosis Bioresearch S.A., Via Lischedi 6592 S.Antonino (CH) Switzerland**)

Decision

The Enlistment Evaluation Committee considered the application/ record and evaluated the application for enlistment of the firm. It was also decided that final notice of one month may be given to the applicant for completion of applications under the rules. In respect of manufacturing authorization in the country of origin or its connectivity with the Principal in USA and their agency agreement.

2. **M/s Atco Healthcare (Pvt.) Ltd., B-18, S.I.T.E., Karachi.**
(Agent of **M/s Rohto Mentholatum Co., Ltd., 16 VSIP, Street 5, Vietnam Singapore Industrial Park, Thuan an Town, Binh Duong Province, VIETNAM**)

Decision

The Enlistment Evaluation Committee considered the application/ record and evaluated the application for enlistment of the firm and required verifications from the drug control organization in the country of origin because investments certificates must be verified by the regulators in the country of origin.

(C) DISCREPANCIES IN THE IMPORT DOCUMENTS OF TWO FIRMS FROM ONE PRINCIPAL MANUFACTURER:-

- (i). **M/s. Graton Pharma, Suit#102, 1st Floor, Plaza, Block-09, Clifton 2-Talwar, Karachi, Pakistan, (Agent of M/s. ESSENTIAL PHARMACEUTICAL, CORP. 1906 W. Holt Avenue Pomona, CA 91768 Dist: Los Angeles, USA)**

- (ii). **M/s. Nutralake Healthcare, Plot # C-105, KDA Scheme # 01, Off Karsaz Road, Karachi-Pakistan, (Agent of M/s. ESSENTIAL PHARMACEUTICAL, CORP. 1906 W. Holt Avenue Pomona, CA 91768 Dist: Los Angeles, USA)**

Both the firms have filed applications from the same principal manufacturer however import documents like Site Master File, Manufacturing License etc have variable contents in these documents. Site Master File of M/s. Graton Pharma and M/s. Nutralake Healthcare have same document number QA 205, revision no. 01, same effective date and review date but differing in number of pages and name of principal manufacturer. In the document of M/s. Nutralake Healthcare Life Saver Solutions, Inc. has been included as prefix to the **M/s. ESSENTIAL PHARMACEUTICAL, CORP.** in the Site Master File as principal manufacturer same is included as suffixed and prefixed in the Free Sale Certificate and Department of Public Health Food and Drug Branch Registration Certificate.

2. Both the firms have filed these documents as legalized by the Notary Public and attested by the Consulate General of Pakistan at Los Angeles and Embassy of Pakistan at Washington DC. The Site Master File of **M/s. Graton Pharma**, contains signatures purported to be made by the qualified technical personnel as a confidential document. Whereas the Site Master File of the **M/s. Nutralake Healthcare**, does not bear such signature. Agency Agreement of the M/s. Nutralake Healthcare has been signed by Mr. Justin Dam on behalf of Life Saver Solutions, Inc. while distribution agreement for USA Health Supply, Inc. has been signed by Dr. Bruce Y Lin as CEO of **M/s. ESSENTIAL PHARMACEUTICAL, CORP.**

3. Decision of 5th Meeting of EEC:-

“The Committee after going through the variability in the import documents of one principal manufacturer i.e. M/s. ESSENTIAL PHARMACEUTICAL, CORP. 1906 W. Holt Avenue Pomona, CA 91768 Dist: Los Angeles, USA presented by the two different agents i.e. (I). M/s. Graton Pharma, Suit#102, 1st Floor, The Plaza, Block-09, Clifton 2-Talwar, Karachi, Pakistan and (II). M/s. Nutralake Healthcare, Plot # C-105, KDA Scheme # 01, Off Karsaz Road, Karachi-Pakistan. Both have presented as attested by the Notary Public and Counter Signed by the Embassy or Consulate of Pakistan. It is concluded that after such verification there exist gray areas which are being manipulated and miss used because one manufacturer registered with same registration No could not have two different particulars. This tantamount that misrepresentation could exist even after present mechanism of attestations. The committee made following decisions.”

(i). Counter verification mechanism by any means and mechanism should be evolved for validation of attested documents.

(ii). Both the firms who presented documents shall be asked to explain their position and their reply shall be placed before the committee for examination and if required firms shall be called upon in the forthcoming meeting of the EEC.

(iii). Cases of importer included in the agenda item III are deferred for further evaluation.

4. Accordingly both the firms **M/s Nutralake Healthcare** and **M/s Graton Pharma** were asked to explain their positions and submit the certified documents. The Principal manufacturers were also contacted through email provided by the both firms. The manufacturers endorsed that both the firms are our clients. It was clarified that principal manufactures Essential Pharmaceutical Corporation is principal manufacture of the products of Life Saver Solutions with health wise logo and we confirm that Nutralake Healthcare of Plot # C-105, KDA Scheme # 01, Off Karsaz Road, Karachi-Pakistan is our exclusive/ sold distribution for dietary supplements for the Territory of Pakistan and Afghanistan.

We are in contract manufacturing agreement with USA Health Supply, Inc. of 3065 S. Jones Blvd Suite # 100, Las Vegas, NV 89164 U.S.A for their products under Private Label with U.S Health Supply logo for their worldwide distribution. USA Health Supply Inc. has appointed **Graton Pharma** with an office at Suite # 102, 1st Floor, The Plaza, Block=09, Clifton 2-Talwar, Karachi Pakistan as an exclusive distributor for US Healthy supply dietary supplements.

We **Essential Pharmaceutical Corp**, are pleased to inform that they are Registered manufacturer with the State of California (Business License # C56119 City of Pomona Account # 00095335) and are also registered with U.S FDA (FDA Registration # 17683297144).

Our operations are fully in accordance with California State laws, FDA regulations, "Public Health Security and Bioterrorism Preparedness and Response Act of 2002" for dietary supplements. There is no such regulation in our knowledge that would prohibit a certified manufacturer like us from any sort of contract manufacturing / Private label.

5. Mr. Mac Choudhary attended the office of the Director (Health & OTC Division) and he verified his signatures as well as signatures of the Dr. Bruce Lin, CEO, **M/s Essential Pharma**. He also countersigned the documents in the presence of Director and DDC (Health & OTC Division) on 10th February, 2016.

6. **M/s Graton Pharma**, submitted that they are also distributor of **M/s Essential Pharmaceutical Corp**, who is legal manufacturer. USA Health Supply Inc. is supplier/ importer and **M/s Graton Pharma**, Karachi has been declared exclusive distributor in Pakistan for their products. They have also undertaken to submit free sale certificate duly issued by the FDA for their products.

Decision

The Enlistment Evaluation Committee considered the applications/ record and previous proceeding of the Committee and decided:

- i) To grant enlistment certificates to **M/s Nutralake Healthcare** on Form-6 based on verification by the Principal Manufacturer.
- ii) Application of **M/s Graton Phamra** was deferred because overseas as well as local contract manufacturing has not been started. Moreover applicant is required to submit exclusive product specific agreement with the Principal Manufacturer along-with free sale certificates for the applied products.

(D) The Firms having agency agreement/ manufacturing authorization of the Principal Manufacturer not attested

Following applications were approved subject to verification of Agency Agreement. It is clarified that Enlistment Certificate to **M/s Tarobina Corporation** as Agent of **M/s Insect Biotec Co. Ltd.**, was already issued to them vide 2nd EEC Meeting, held on 21-09-2015. Whereas agency agreement with **M/s Feed Up Ltd**, have been submitted but letter could not be issued due to variation in the address of principal manufacturer in the manufacturing license, site master file and GMP certificate. So the issuance of letter was held in abeyance till clarification.

Decision

- i) The Enlistment Evaluation Committee considered the application/ record and withdrawn the approval of enlistment certificates to **M/s Tarobina Corporation** as Agent of **M/s Insect Biotec Co. Ltd.**, was already issued to them vide 2nd EEC Meeting, held on 21-09-2015.
- ii) The approval for enlistment of **M/s Tarobina Corporation** as Agent of **M/s Feed Up Ltd**, Korea is linked with the clarification from the firm regarding variation in the address of the firm in the Master File, manufacturing license and GMP certificates. If clarification is unsatisfactory the approval shall stands withdrawn.

(E) The Firms having agency agreement/ manufacturing authorization of the Principal Manufacturer not attested

Following cases were approved subject to submission of agency agreement/ manufacturing authorization dully attested by the relevant embassy/ consulate

1. **M/s ICI Pakistan Limited, ICI House, 5 West Wharf, Karachi.
(Agent of M/s Inform Nutrition Ireland Ltd, Whites Cross, Cork, Co Cork, IRELAND) (Veterinary use)**
2. **M/s Bristol Mayer Biotech, 69-A, Guldasht Town, Zarar Shaheed Road, Lahore Cantt. has submitted registration certificate with FDA, USA. Manufacturing authorization from the country of origin not submitted. (Agent of M/s Officina Farmaceutica Italiana, S.P.A. -Via Verga, 14-24127-Bergamo ITALY) (Human use)**

Decision of 7th Meeting of EEC

The Enlistment Evaluation Committee considered the application/ record and evaluated the application for enlistment of the firm and granted approval for Enlistment Certificates on Form-6 subject to provision of manufacturing authorization from the country of origin.

Decision

- i) The conditional approval for enlistment certificates of both firms have become in fructuous because both firms failed to submit the required documents. It was also decided that the case may be deferred and both firms may be given final notice for submission of requisite documents and resubmitted to the Enlistment Evaluation Committee.

(F) The Firms having agency agreement/ manufacturing authorization of the Principal Manufacturer not attested

**M/s Tianshi International Pak. Co. (Pvt) Ltd. 1st Floor, Banner Store Shopping Plaza, Block 20-A, Main Civic Centre, G-8 Markaz, Islamabad.
(Agent of M/s Tianjin Tianshi Biological Development Co., Ltd. No. 16 Xinyuan Road, Wuqing Development Area, Tianjin, CHINA) (Human use)**

Decision of 7th Meeting of EEC

The Enlistment Evaluation Committee considered the applications/ record and evaluated the application for enlistment of the above firm and granted approval for Enlistment Certificates on Form-6 subject to provision of manufacturing authorization / attested agency agreement by the abroad Principal Manufacturer.

Accordingly M/s Tianshi International Pak. Co. (Pvt.) Ltd. was asked to provide attested copy of manufacturing authorization and agency agreement of the dully

verified by the principal manufacturer as per undertaking dated 21-01-2016. They were also reminded to submit copy of Drug Sale License as per their undertaking dated 11th January, 2016. M/s Tianshi International Pak. Co. (Pvt.) Ltd. submitted letter of authorization from the principal manufacturer M/s Tianjin Tianshi Biological Development Co. Ltd. China which was unsigned. They also failed to submit the Tianjin food and drug administration manufacturing authorization as per undertaking. Accordingly they were also once again reminded vide this Division letter dated 19-02-2016 to submit attested copies of FDA License and Drug Sale License. Moreover it was also asked to submit agency agreement with the principal manufacture dully signed and attested.

Misleading Statements

1. M/s Tianshi International Pak. Co. (Pvt.) Ltd., submitted misleading statements vide their letter dated 10-02-2016 and 22-02-2016 wherein they claimed as under: -
 - i) That the authorization from FDA is submitted in original which contains, the stamp of the legal representative of the company, the stamp of the authority of Notraization department of the government of China and Original attestation from the embassy of Pakistan in Beijing. Furthermore it is worth mentioning to bring into your kind notice that in China signature stamp of the authorized person is used. (copy of the letters submitted in this regard are attached herewith)
 - ii) That the copy of sale license issued by the ICT, Health Department is attached herewith.
2. The facts of the case are that M/s Tianshi International Pak. Co. (Pvt.) Ltd. failed to submit the following documents: -
 - i) Manufacturing License dully issued by the Tianjin FDA and attested by the Embassy of Pakistan.
 - ii) The authorization letter from the principal manufacturer was unsigned.
 - iii) Drug Sale License has not been issued to the applicant till 25th February, 2016 because it was also verified from the ICT, Health Department, Islamabad, but the applicant claim twice that drug sale license is attached.
3. It is also worth mentioning that investigations are underway before the Chief Commissioner, Islamabad on the direction of Islamabad High Court. Chief Commissioner Court issued Summon in case No.27/2015 filed by Mr. Irfan Nazir vs Tiens etc. which is pending in the court of Chief Commissioner, Islamabad. Moreover Security Exchange Commission of Pakistan has also initiated winding up proceeding under the provision of company ordinance 1984, and filed petition in the court of competent jurisdiction for wining up of the company.

Decision

After detailed evaluation of documents filed by the firms for the grant of enlistment, the Enlistment Evaluation Committee decided to reject the application on the following grounds:

- i) The applicant failed to complete the formalities despite undertaking to submit the certified import documents from the Principal Manufacturer.
- ii) Applicant filed misleading information twice that the drug sale license attached but the said documents have not been issued. It was also verified from the ICT Health Department.
- iii) The Court of Chief Commissioner, Islamabad issued notice to the DRAP vide case No.27/2015 filed by Mr. Irfan Nazir vs Tiens, Islamabad. The said case have been taken up on the direction of Islamabad High Court about unethical marketing practices and other complaints.
- iv) Security Exchange Commission of Pakistan has also initiated winding up proceedings against the company under the provision of companies ordinance 1984. A copy of the order sanctioning filing of wining up petition against the company was issued by the Commission which is available the website and a copy thereof containing detail background of the case was also enclosed to the Assistant Commissioner/ Sub Divisional Magistrate, Industrial Area, Islamabad.
- v) It was also decided the company may apply a fresh after fulfillment of codal formalities and clearance from the SECP as well as from the Court of Chief Commissioner, Islamabad.

ITEM NO. 4:- MISCELLANEOUS CASES:-

1. Product Applications for the Grant of Enlistment.

Enlistment Evaluation Committee has already constituted sub-committee for evaluation of products applications. The Committee has also developed check lists for applications filed on Form-3, Form-4 and Form-5. Keeping in view the expediency of court cases, the Committee may be authorized to issue enlistment certificates of generic formulations which are registered locally or marketed in the developed countries after evaluation by the stringent regulatory authorities (SRA) countries. However it is the responsibilities of the applicant to produce evidence in this regard.

Decision:-

The Committee authorized the sub-committee constituted for product enlistment to issue product enlistment certificates for the generic products which are registered locally or on free sale on the market of SRA Countries. It was also decided that single ingredient products will be enlisted without brand names. It was also decided that Unani/ Herbal/ Homoeopathic Products appearing in the respective authoritative books/ pharmacopeias will be enlisted as per name appearing in the relevant book. Compound formulation would be allowed to be registered under the brand names.

2. **Incomplete Applications:-**

List of firms/ companies whose applications are incomplete. Local Manufacturing (**Annex-A**) and Import (**Annex-B**) submitted for consideration of EEC.

Decision:-

The Committee after examination of cases decided to reject the applications under Rule 7 on the grounds that applicant failed to complete their applications as per prescribed criteria under the Rules despite notices of shortcomings/ deficiencies.

Disclaimer:

Errors/ omissions/ mistakes may be reported to the Director (Health & OTC Division) for corrections.

Pakistan Zindabad