

## Minutes of the 9th Meeting of EEC held on 04-04-2016

No. F. 10-03/2016-DDC (Health & OTC)  
Government of Pakistan  
Ministry of National Health Services, Regulations & Coordination  
**DRUG REGULATORY AUTHORITY OF PAKISTAN**

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Islamabad, the 4<sup>th</sup> April, 2016

### MINUTES OF THE 9<sup>TH</sup> MEETING OF ENLISTMENT EVALUATION COMMITTEE FOR ALTERNATIVE MEDICINES AND HEALTH PRODUCTS

9<sup>th</sup> 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 4<sup>th</sup> April, 2016. Meeting of Committee was attended by the following:-

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

## Minutes of the 9th Meeting of EEC held on 04-04-2016

**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.	<b>M/s Hiranis Pharmaceuticals (Pvt.) Ltd.,</b> E-145-149, North Western Industrial Zone, Port Qasim, Karachi 75020.	1. Tablet 2. Capsule 3. Powder Sachet/ Dry Syrups 4. Oral liquid (Syrup)/ Sachet/ Drops 5. Liquid Mouthwash 6. Ointment/ Cream/Tooth Paste
2.	<b>M/s Safrin Skin Care International,</b> 1st and 2nd Floor, 33-Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.	1. Ointment/ Cream
3.	<b>M/s Dr. Zia Homoeopathic Pharma DZHP,</b> Plot No. 18, Sector - 14 Korangi Industrial Area, Karachi.	1. Oral liquid (Syrup)/ Drops 2. Cream/ Ointment 3. Mother Tincture
4.	<b>M/s MINT Pharmaceuticals (Pvt.) Ltd.,</b> 10.2-km Sheikhpura Road, Lahore.	1. Oral liquid (Syrup) 2. Tablet 3. Lozenges 4. External preparation (cream/ ointment) 5. Sachet
5.	<b>M/s Nigehban,</b> Plot No. 82, Liaquat Square, Malir Township, Malir Industrial Area, Karachi.	1. Semisolid/ medicated cosmetics 2. Oral liquid (Syrup & drops etc.) 3. Capsule 4. Tablet 5. Lozenges 6. Sachet 7. Medicated soaps
6.	<b>M/s Montis (Pvt.) Ltd.,</b> Katar Bund Road, Jinnah Industrial Area, Tokhar Niaz Baig, Lahore.	1. Tablet 2. Dry powder (sachet) 3. Capsule 4. <b>Semisolid</b> preparations (cream/ ointment/ lotion/ gel & medicated shampoo)
7.	<b>M/s Derma Pride, Manufactures of Cosmetic &amp; Skin Clinic Products,</b> 537-A, Sundar Industrial Estate, Lahore.	1. Medicated Soaps 2. Semisolid (cream/ lotion/ gels) 3. Medicated shampoos

## Minutes of the 9th Meeting of EEC held on 04-04-2016

8.	<b>M/s Blossom Laboratories (Pvt.) Ltd.</b> , 30-KM, Badian Road, ½ K.M Off Roda Bohgal Road, Lahore Cant.	<ol style="list-style-type: none"> <li>1. Tablet</li> <li>2. Capsule</li> <li>3. Dry Powder</li> <li>4. Oral liquid (syrup)</li> </ol>
9.	<b>M/s Dew Natural Pharma</b> , 9-Km Sheikhupura Road, Muridkey	<ol style="list-style-type: none"> <li>1. Tablet</li> <li>2. Oral liquid (syrup)</li> </ol>
10.	<b>M/s Focus &amp; Rulz Healthcare Division</b> , Plot No. 44, Industrial Triangle Kahuta Road, Islamabad.	<ol style="list-style-type: none"> <li>1. Capsule</li> <li>2. Cream/ ointment</li> <li>3. Sachet</li> <li>4. Oral liquid (syrup)</li> <li>5. Tablet</li> </ol>
11.	<b>M/s Galen Nutraceuticals</b> , Plot No. 10, Street No. 3, I-10/3, Islamabad.	<ol style="list-style-type: none"> <li>1. Cream/ ointment</li> </ol>
12.	<b>M/s Le Grand Vertex</b> , 30, Sundar Industrial Estate, Sundar, Lahore.	<ol style="list-style-type: none"> <li>1. Tablet</li> <li>2. Topical (Cream/ Ointment/ Lotion/ Shampoo)</li> <li>3. Capsule</li> <li>4. Dry powder &amp; sachet</li> </ol>
13.	<b>M/s Paragon Herbal Laboratories</b> , Plot No. Kht 285, Ktn 570, Allah Hoo Industrial Area, Near Sabzi Mandi, Gujumatta, Ferozepur Road, Lahore.	<ol style="list-style-type: none"> <li>1. Oral liquid (syrup)</li> <li>2. Capsule</li> <li>3. Tablet</li> </ol>

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

1.	<b>M/s Aftab Qarshi Dawakhana</b> , Muzammal Town, 20 Km Multan Road, Chung, Lahore.	17-02-2016	<ol style="list-style-type: none"> <li>01. Dr. Hafiz Muhammad Asif, Member EEC</li> <li>02. Mr. Ajmal Sohail Asif, FID, DRAP, Lahore.</li> </ol>	Not Good	Committee rejected the application due to the reasons given in the Inspection Report by the panel.
2.	<b>M/s Bio Roots Laboratories (Pvt.) Ltd.</b> , Opposite NIZ Chamber Mor GT Road, Rawat, Rawalpindi.	10-03-2016 & 29-03-2016	<ol style="list-style-type: none"> <li>01. Dr. Abdur Rashid, DDG (E&amp;M), DRAP, Islamabad.</li> <li>02. Mr. Khalid Mahmood, FID-II, DRAP, Islamabad.</li> </ol>	Not Good	Committee rejected the application due to the reasons given in the Inspection Report by the panel.

## Minutes of the 9th Meeting of EEC held on 04-04-2016

### **3. INSPECTION REPORT WILL BE SUBMITTED AFTER RE-INSPECTION BY THE PANEL:-**

1.	<b>M/s Amaranth Health Care</b> , Plot No. 168, Sector 23, KIA, Karachi.	01-03-2016	01. Dr. Saif-ur-Rehman Khattak, FGA, CDL, DRAP, Karachi.  02. Dr. Shoaib Ahmed, ADC, DRAP, Karachi.		Committee rejected the application due to the reasons that there is no provision under the rules to give three months time for re-inspection. However the applicant may apply afresh after fulfillment of legal requirements and his case will be taken on priority basis.
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### **Decision**

1. 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).
2. **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.

## **Minutes of the 9th Meeting of EEC held on 04-04-2016**

### **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 Chakwal Pharma International**, OTI Plaza, 210, Lalazar Commercial Market, ThokarNiazBaig, Raiwind Road, Lahore.  
(Agent of **M/sMedivet Laboratories**, Headquarter 159 Avenue de l'UMA, Residence les mimosas, Soukra, **TUNISIA**)
2. **M/s Jawad Impex International**, 21-Iftikhar Building, Chouburji, Lahore.  
(Agent of **M/s Impextraco NV**, Wiekevorstsesteenweg 38 B-2220 HEIST-OP-DEN-BERG, **Belgium**)
3. **M/s Phar-Man Services**, Plot No. 226, Sector 27, Korangi Industrial Area, Karachi.  
(Agent of **M/s Weber & Weber International GmbH & Co. KG**, HerrschingerStr 33, 82266, Inning am Ammersee, **Germany**)
4. **M/s Phar-Man Services**, Plot No. 226, Sector 27, Korangi Industrial Area, Karachi.  
(Agent of **M/s GehrlicherPharmazeutischeExtrakte GmbH**, Robert – Koch Str. 5, D-82547, Eurasburg / Obb **Germany**)
5. **M/s Nutrix Health Care**, Plot No. 44, St # 03, Small Industrial, 9Km Samundri Road (Phata Stop) Faisalabad.  
(Agent of **M/s LiaochengAojian Biotechnology Co., Ltd.**, Site No. 88 Huaxin Road, Guhe Industrial Park, Gaotang Country, LiaoCheng city, Shandong Province, **CHINA**)
6. **M/s RG Pharmaceutica (Pvt.) Ltd.**, 703, RogressiveSquire, P.E.C.H.S, Block 6,Shahra-e-Faisal, Karachi.  
(Agent of **M/s Cerbios-Pharma SA**, Via Figino 6, CH-6917 Barbengo/ Lugano **SWITZERLAND**)
7. **M/s Ghazi Brothers**, Ghazi House, D-35, KDA Scheme No. 1, Miran Muhammad Shah Road, Karachi.  
(Agent of **M/s LG Life Sciences, Ltd.**, 58, Saemunan-ro, Jongno-gu, Seoul, **KOREA**)
8. **M/s Fartal Pharmaceuticals**, Plot No. 9, Street No. 1, Model Colony, Karachi.  
(Agent of **M/s PFO Vetos-Farma sp.zo.o**,58-260 Bielawa, 21 DzierzoniowskaStr.**POLAND**)

## Minutes of the 9th Meeting of EEC held on 04-04-2016

9. **M/s Angelini Pharmaceuticals (Pvt.) Ltd.**, 221 Block CCA, Phase 4, DHA, Lahore.  
(Agent of **M/s IBSA FARMACEUTICI ITALIA S.R.L.** Via Martiri di Cefalonia, 2 – 26900 LODI (LO) ITALY)
10. **M/s Agro Poul Vet International**, 1/12-A, Sheet No. 24, Model Colony, Karachi.  
(Agent of **M/s Inner Mongolia Huatian Pharmaceutical Co., Ltd.** Economic Development zone, Yuanhbaoshan District, ChiFeng city, Inner Mongolia, P.R. CHINA)
11. **M/s Shaigan Pharmaceuticals (Pvt.) Ltd., (Health Care Division)** 14-Km Adyala Road, Rawalpindi.  
(Agent of **M/s Shandong Yuwang Pharmaceutical Co., Ltd.** No. 2731, The North of Tongqu Road, Yucheng City, Shandong. CHINA)  
**(The said principal has already been enlisted for other companies too)**
12. **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)
13. **M/s AWH Pharma**, Plot No. 224/B, Office No. 2, 2<sup>nd</sup> Floor, Commercial Centre, Satellite Town, Rawalpindi.  
(Agent of **M/s Nutrition Group PLC**, 316 Blackpool Road, Fulwood, Preston Lancashire PR2 3AE)
14. **M/s Sind Medical Stores**, 13-B, Block 6, PECHS, Shahrah-e-Faisal, Karachi.  
(Agent of **M/s Nutriset**, Hameau du Bois ricard – CS 80035, 76770 Malaunay, FRANCE)  
**(Only for one product Plumpy Nut manufactured by Nutriset, France)**
15. **M/s Bayer Pakistan (Pvt.) Limited**, C-21 S.I.T.E., Karachi.  
(Agent of **M/s Delpharm Gaillard**, 33 rue de l'Industrie, 74240 Gaillard, FRANCE)
16. **M/s Ferozsons Laboratories Limited**, Amargarh, Nowshera, Khyber Pakhtunkhwa.  
(Agent of **M/s TwoPac AB**, Vindelvagen 3, SE 241 38 Eslov, SWEDEN)
17. **M/s Ferozsons Laboratories Limited**, Amargarh, Nowshera, Khyber Pakhtunkhwa.  
(Agent of **M/s Farmasierra Manufacturing S.L.** Carretera de Irun Km. 26,200 28700 San Sebastian de los Reyes, Madrid, SPAIN)
18. **M/s Kaap Pharmaceuticals**, 18-KM Ferozepur Road, Lahore.  
(Agent of **M/s Nabros Pharma Pvt. Limited**, National Highway No. 8, Kheda – 387411, Gujrat, INDIA)

## **Minutes of the 9th Meeting of EEC held on 04-04-2016**

19. **M/s Novamed Healthcare Pvt. Ltd.**, 28-Km Ferozepur Road, Lahore.  
(Agent of **M/s SIRIO Pharma Co. Ltd.**, No. 83, Taishan Road, Shantou, Guangdong, **CHINA 515041**)  
**(The said principal has already been enlisted for other companies too)**
20. **M/s Z/Y Corporation**, Plot No. 18, Sector 14, Korangi Industrial Area, Karachi.  
(Agent of **M/s S.C. PlantExtrakt S.R.L.**, Radaia village, Baciú, Cluj country, **Romania**)
21. **M/s Tarobina Corporation**, 226-Ahmed Block New Garden Town, Lahore.  
(Agent of **M/s Special Nutrients inc. USA**, 27660SW037TH Avenue, Miami Florida, 33133, **USA**)
22. **M/s AGP (Private) Limited**, B-23 S.I.T.E., Karachi.  
(Agent of **M/s BioGrowing Co., Ltd.**, No. 10666, Songze Rd, Qingpu, Shanghai, 201700, **CHINA**)  
**(The said principal has already been enlisted for other companies too)**
23. **M/s Kurative Green**, C-51, DarulAman Society, Haider Ali Road, Near Hill Park, Karachi.  
(Agent of **M/s SIRIO Pharma Co. Ltd.**, No. 83, Taishan Road, Shantou, Guangdong, **CHINA 515041**)  
**(The said principal has already been enlisted for other companies too)**
24. **M/s Atco Healthcare (Pvt.) Ltd.**, B-18, S.I.T.E., Karachi.  
(Agent of **M/s SIRIO Pharma Co. Ltd.**, No. 83, Taishan Road, Shantou, Guangdong, **CHINA 515041**)  
**(The said principal has already been enlisted for other companies too)**
25. **M/s Al-Hamd Poultry & Livestock Services**, U-31 KhudaBuksh Colony, Lahore Cant.  
(Agent of **M/s Andres Pinaluba, S.A.**, Industrial Area Agro Reus, PrudenciBertrana, nr 5 43206 Reus, **SPAIN**)
26. **M/s Al-Hamd Poultry & Livestock Services**, U-31 KhudaBuksh Colony, Lahore Cant.  
(Agent of **M/s SimbiyotekBiyolojikUrunler San.VE TIC. A.S.** Olkul C.26/1, Orhanli, Tuzla/Istanbul/ **TURKEY**)
27. **M/s Vetmed (Regd)**, 22-A, Sharae Fatima Jinnah, Lahore.  
(Agent of **M/s EWABO Chemikalien GmbH & Co. KG**, Office Kolpingstraße 4, DE-49835 Wietmarschen, **GERMANY**)
28. **M/s Delta Pharma**, P.K. Wasvani Building, Arambagh, Karachi.  
(Agent of **M/s Mayons Pharmaceuticals Pvt Ltd.**, Kalamnabasti, Behind Octroi no 4, old Kamptee Road Kalamna, Nagpur-440002, Dist." Nagpur (Paharashtra) **INDIA**)

## Minutes of the 9th Meeting of EEC held on 04-04-2016

29. **M/s The Vitamin Company**, FF-27, Center Point, Gulberg III, Lahore.  
(Agent of **M/s Alaska Spring Pharmaceutical**, 609-5 Cantiague Rock Rd, Westbury, NY 11590 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. It was also decided that product specific free sale certificates shall be required for the Importers who want to import from the principal having multiple agreements with the Pakistani Importers. Only one similar formulation could be enlisted into Pakistan for a particular product by any of the agent.

### **B. Applications having certain deficiencies.**

1. **M/s Harum Pharma**, 12-F-1, Aleem Centre (1st Floor) Main Rashid Minhas Road, Gulshan-e-Iqbal, Block-5, Karachi-75300-Pakistan.  
(Agent of **M/s Advanced Agrochemical and Veterinary Products Industrial Co. (CHEMVET) JORDAN**)  
**Attested copy of original Agency Agreement required.**
2. **M/s Darul Adviat**, B-87, Block-D, North Nazimabad, Karachi-74700  
(Agent of **M/s Dr. Willmar Schwabe India Pvt. Ltd.**, A-36, Sector-60, Phase-III, Noida-201304, GautamBudh Nagar (U.P.), **INDIA**)  
**Attested copy of original Agency Agreement required.**
3. **M/s High Class Pharma**, 89-A, Canal View Society, Lahore.  
(Agent of **M/s Hankkija Oy**, PL 390, 05801 Hyvinkaa, **FINLAND**)  
**(Notarized undertaking required)**
4. **M/s ICI Pakistan Limited**, ICI House, 5 West Wharf, Karachi.  
(Agent of **M/s Pronova BioPharma Norge AS**, Framnesveien 41, No.-3222 Sandefjord, **NORWAY**)  
**Attested copy of original Agency Agreement required.**
5. **M/s Bayer Pakistan (Pvt.) Limited**, C-21 S.I.T.E., Karachi.  
(Agent of **M/s Berlimed, S.A.** Poligono Industrial Santa Rosa c/Francisco Alonso, 7 28806 Alcala de Henares (**Madrid**), **SPAIN**)  
**(Manufacturing authorization from the regulatory authority is required as claimed in the site master file at page 6 No.26.00006987/M)**
6. **M/s Orient Animal Health Pvt Ltd.**, Commercial-6, 1st Floor, Block' A, Kazimabad, Near Masjid-e-Hira, Model Colony, Karachi.  
(Agent of **M/s Univet Ltd.**, Tullyvin, Cootehill, Co., Cavan, **IRELAND**)  
**(Manufacturing authorization of the Principal manufacturer is required)**



## **Minutes of the 9th Meeting of EEC held on 04-04-2016**

7. **M/s Hameed Organisation**, 2<sup>nd</sup> Floor, Al-Khaleej Towers, Shaheed-e-Millat Road, Karachi.  
(Agent of **M/s Bhargava Phytolab Pvt. Ltd.**, E-1216, Phase – 1, Extn., Ghatal, Bhiwadi Industrial Area, Bhiwadi (Raj.) **INDIA**)  
**(Firm registration and NTN certificates required)**
8. **M/s SS Associates**, 8/10, Jail Road, Lahore.  
(Agent of **M/s Medicave Tarim Hayvancihklacve Kimya San. Tic. Ltd. Sti.** ITOSB Eski Ankara Asfalti 34969 12.Cadde No.: 1 Tepeoren Tuzla / **ISTANBUL, TURKEY**)  
**(Attested copy of original Agency Agreement required)**
9. **M/s Axis Healthcare**, 6-B Value addition city Khurrianwala, Faisalabad.  
(Agent of **M/s SIRIO Pharma Co. Ltd.**, No. 83, Taishan Road, Shantou, Guangdong, **CHINA 515041**)
  - i. **The said principal has already been enlisted for other companies too.**
  - ii. **Application form and fee are photocopies which need verification**
10. **M/s Nova Medicines (Pvt.) Ltd.**, 406, Panorama Centre No. 2, Raja Ghazanfar Ali Khan Road, Saddar, Karachi.  
(Agent of **M/s Korea United Pharm. Inc.**, 22, Nonhyeon-ro 121-gill, Gangnam-gu, Seoul, **KOREA**)  
**(Notarized undertaking is not available)**

### **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, subject to fulfillment of codal formalities/ deficiencies notified above.

### **C. Applications wherein import documents reveal that the products are medical devices in the country of origin.**

1. **M/s Apsta International**, 2-A/5, Shimla complex, 11-Durand Road, P.O Box No. 1058, Lahore.  
(Agent of **M/s Laboratorium Dr. Deppe GmbH**, in Kempen (Amtsgericht Krefeld, HRB 13516 **Germany**)
2. **M/s Bristol Mayer Biotech**, 69-A, Guldasht Town, Zarar Shaheed Road, Lahore Cant.  
(Agent of **M/s Purna Pharmaceuticals N.V.**, Rijksweg 17, Industriepark Zone Puurs 2870 Puurs, **BELGIUM**)

## **Minutes of the 9th Meeting of EEC held on 04-04-2016**

3. **M/s Medinostic Health Care (Pvt.) Ltd., B-18, S.I.T.E., Karachi.**  
(Agent of **M/s Pal International Ltd, Bilton Way Lutterworth Leicestershire LE 17 4JA United Kingdom**)

### **Decision**

The Enlistment Evaluation Committee considered the applications/ record and deferred the applications for further evaluation.

#### **(D) Application for Enlistment as agent of abroad Principal Manufacturer meeting the prescribed criteria**

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

### **Background of the Case:**

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.

The firm has obtained legalized attested Import documents from Counsel General of Hongkong and is submitting the papers on 04-04-2016.

### **Decision**

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

#### **(E) DRUG MANUFACTURING LICENSE INSTEAD OF DIETARY SUPPLEMENT MANUFACTURER REGISTRATION.**

Following firms have submitted attested copies of Drug Manufacturing License. FDA was requested through email that whether Drug Manufacturing License could be use for manufacturing for Dietary Supplement. FDA responded that FDA grants registration certificate to the manufacturers of dietary

## **Minutes of the 9th Meeting of EEC held on 04-04-2016**

supplement under the food category and drug manufacturing license is not valid for such products. They also said that they not issue any GMP Certificate nor rely on the GMP Certificate issued by the private sectors.

- (i). M/s. **Heal The World**, City Centre Suite 107, Marston Road, Karachi-Pakistan.  
(Agent of M/s. Robinson Pharma, Inc. 3330 South Harbor Boulevard, Santa Ana, California 92704, U.S.A.).

### **Basic decision:-**

1. Exclusive Sole Agency Agreement shall be provided from the Principal Manufacturer for the products / formulations which are on Free Sale and authorized to be marketed in the local market.
2. Countries like USA where Nutraceuticals products or Dietary Supplements or Health Supplements are categories separate from the Allopathic Drugs, Drug Manufacturing License will not be acceptable as manufacturing authorization. Relevant manufacturing authorization from the regulatory authority shall be submitted by the applicant.
3. Manufacturing Authorization as drug shall be submitted by the applicants from the regulatory authorities where the Herbal products are categorized as drugs like EU Countries.
4. Manufacturing units having both type of facilities shall be required to submit both authorizations, otherwise only the products of the facility whose manufacturing authorization have been submitted will be entrusted for enlistment.
5. Only applicants having Sole Agency Agreement for the product with Principal Manufacturer / Legal Owner abroad will be entrusted.
6. Valid GMP Certificate issued by the regulatory authority based on inspection report shall be sufficient to replace inspection report. Otherwise inspection report by the regulatory authority shall be required to be submitted for enlistment.
7. This decision will be applicable on all the applicants, in item 4, item 5 sub item 1 & 2 and already enlisted firms.

Accordingly four applicants were communicated above decision. M/S Heal the world Karachi has submitted following documents.

- I. Registration Certificate from state regulatory Authority as manufacturer of Dietary supplements.
- II. Exclusive Agency agreement with the Robinsons Pharma Karachi which is product specific.
- III. Free sale certificate for the products.
- IV. Manufacturer certificate for Pakistan.

### **Decision**

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

## **Minutes of the 9th Meeting of EEC held on 04-04-2016**

### **(F) M/S TIANSHI INTERNATIONAL PAK. CO. (PVT) LTD**

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

### **Background of the Case**

Enlistment Evaluation Committee in its 8<sup>th</sup> Meeting 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.

Accordingly decision of the Committee was conveyed to the applicant who filed fresh application and completed the formalities. However as per decision of the Committee in its 8<sup>th</sup> meeting clearance from the Chief Commissioner, Islamabad Court and SECP is not submitted. The

## Minutes of the 9th Meeting of EEC held on 04-04-2016

applicant claimed that he has completed all the formalities and clearance from the Chief Commissioner, Islamabad and SECP is not legal requirement for him.

### **Decision**

The Enlistment Evaluation Committee considered the application/ record and evaluated the application for enlistment of the above firms and granted approval for Enlistment Certificates on Form-6, subject to clearance from the Chief Commissioner, ICT Court and SECP who are making investigations under the directions of Islamabad High Court, Islamabad.

### **ITEM: - IV Objectionable Products:-**

Products whose enlistment certificates with held due to reasons mentioned against each:

S. No.	Applicant	Product along-with composition	Reasons to with hold	Decision of EEC
1	M/s Glorious Laboratories, Islamabad.	<b>ViD-3 Capsule</b> Contains Cholecalciferol....100,000IU	The content of vitamin D is above the upper tolerable limit recommended for food supplement.	EEC deferred the applications for personal hearing along-with evidence / justification that these products are alternative medicines or health products (food supplements) in the applied formulation and strength.
2	M/s Glorious Laboratories, Islamabad.	<b>D Cure Capsule</b> Vitamin D2.....20000IU Vitamin E.....50mg	-do-	-do-
3	M/s Glorious Laboratories, Islamabad.	<b>Glo&amp; Grow Spray</b> Minoxidil.....5%	It does not come under the definition of Alternative Medicines or Health & OTC Products.	-do-
4	M/s Wilson's Healthcare	<b>Orchard Syrup Smokers</b> Each 5ml Contains: Pelargonium Sidoides(Eu.P).....13 mg European pharmacopeia Specifications	One brand of similar formulation was given to the firm. 2 <sup>nd</sup> brand of same formulation could not be given.	-do-
5	-do-	<b>Serotin SR Capsules 40000 IU</b> Each Capsule Contains: 1) Serrapeptase.....40000 IU	Product containing Serratiopeptidase is available as enteric coated capsule or tablets dosage form. Neither non enteric coated nor are SR capsules	-do-

**Minutes of the 9th Meeting of EEC held on 04-04-2016**

			available locally or internationally. You are requested to produce evidence for such availability if any. But applicant could not provide evidence.	
6	-do-	<b>Serotin SR Capsules 80000 IU</b> Each Capsule Contains: 1) Serrapeptase.....80000 IU	-do-	-do-
7	-do-	<b>Serowil Capsules 80000 IU</b> Each Capsule Contains: 1) Serrapeptase.....80000 IU Specification monograph	-do-	-do-

**ITEM NO. V:- 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 Enlistment Evaluation Committee after evaluation made decisions as stated for each products in column 6 of Annexure-A.

**Disclaimer:**

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

**Pakistan Zindabad**