

## Minutes of the 11th Meeting of EEC held on 13-05-2016

No. F. 10-05/2016-DDC (Health & OTC)  
Government of Pakistan  
Ministry of National Health Services, Regulations & Coordination  
**DRUG REGULATORY AUTHORITY OF PAKISTAN**

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Islamabad, the 13<sup>th</sup> May, 2016

### MINUTES OF THE 11<sup>TH</sup> MEETING OF ENLISTMENT EVALUATION COMMITTEE FOR ALTERNATIVE MEDICINES AND HEALTH PRODUCTS

**11th** 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 **13<sup>th</sup> May, 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 <b>-Not Present-</b>
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
8.	<b>Mr. Muhammad Amin,</b> Deputy Director (PER Division)	Observer
9.	<b>Mr. Adnan Faisal Saim,</b> DDC, QC (1&2)	Observer

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**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.

<b>S. No.</b>	<b>Name and address of the Manufacturer</b>	<b>Name of approved Sections/ Decision</b>
1.	<b>M/s. Medicom Superior,</b> 122-A, Muzammal Town, Chung, Multan Road, Lahore.	Deferred for verification of address which are contradictory as under <b>1. <u>As per Master File and Inspection Report:</u></b>  122-A, Muzammal Town, Chung, Multan Road, Lahore.  <b>2. <u>Factory Address as per application Form-1 and allotment letter:</u></b> 79-Sunder Industrial Estate, Lahore.
2.	<b>M/s. Savoir Pharma,</b> 3-S, Quaid-e-Azam, Industrial Estate, Lahore.	1. Tablet
3.	<b>M/s New Shaheen Pharma,</b> Commercial-13, Block-A, Kazimabad, Model colony, Malir, Karachi.	Deferred for inspection by the panel nominated in the letter issued from the Division of Health & OTC products, because as verified by the DDC, QC (Mr. Adnan Faisal Saim) representing QC Division that Mr. Obaid Ali is Area, FID for Malir, Karachi where the facility exists.
4.	<b>M/s. Hale Pharma,</b> B- Kh No. 285, Kh No. 570 Allah Hoo Industrial Estate, Allah Hoo Pul 22 Km Ferozpur Road, Lahore.	1. Tablet 2. Oral Liquid 3. Dry Powder Sachet 4. Capsule 5. Topical Semisolid (Cream / Ointment)
5.	<b>M/s. PDH Health Care,</b> 42-Nicholson Road, Lahore.	Rejected based on observations by the panel of inspectors.
6.	<b>M/s Genbiotch Nutraceuticals,</b> Plot No. 24, Street No. NS-2, NIZ RCCI, Rawat, Rawalpindi.	Deferred on the basis of letter dated 25 <sup>th</sup> April, 2016 of the Firm, cutting and overwriting in the inspection report are signed by one Member only, two visits by the panel needs justification. Case is deferred for verification by the both panel members.

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7.	<b>M/s Botanica Herbal Lab,</b> Near Imtiaz Market, Main Lakho Road, Chakra, Rawalpindi.	1. Oral liquid (syrup/ solution) (Contract manufacturing not allowed for the time being)
8.	<b>M/s Hikam Industries,</b> 35-Km, Main Ferozpur Road, Lahore.	1. Tablet 2. Dry Powder Sachet 3. Oral liquid (Syrup ) Herbal (Semisolid Balm section is not approved because it is not mentioned in the layout plan).

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

1.	<b>M/s. Altmed Laboratories,</b> 46-M, Quaid-e-Azam Industrial Estate, Lahore.	02-05-2016	01. Dr. Sheikh Akhtar Hussain, DDG (E&M), DRAP, Lahore.  02. Mr. Asif Rauf, FID, DRAP, Lahore.	Not Good	Committee rejected the application due to the reasons given in the Inspection Report by the panel.  "The firm M/s Neutrimed formerly Altmed in built in industrial area. Two halls have been converted into unit on a leased premises (formerly for almost one year & extendable to 5 years). The upper storage had roofs of Izhar limited. The flow, building floor, walls were found suitable. The stores were congested & without temperature measure. Environment conditions were not maintained in raw material / finished good capsule, liquid syrup section etc., Q.C was being operated by pharmacist having 1 year experience.
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### Decision

"Deferred till forthcoming meeting due to constraint of time"

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

#### **A. CORRECTION IN THE MINUETS OF THE 10<sup>TH</sup> MEETING OF EEC.**

1. **M/s ATCO Healthcare (Pvt.) Ltd.**, B-18, S.I.T.E., Karachi. (Agent of M/s Rohto Mentholatum Co., Ltd., No. 16 VSIP, Street 5, Vietnam Singapore Industrial Park, Thuan an Town, Binh Duong Province, VIETNAM)

#### **Decision of 8<sup>th</sup> Meeting of EEC:**

“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.”

Now the Ministry of Health have certified that Rohto-Mentholatum (Vietnam) Company Ltd., No. 16 VSIP, Street 5, Vietnam Singapore Industrial Park, Thuan an Town, Binh Duong Province, VIETNAM is in the field of practice of finished medicine not containing antibiotic b-Lactam in the dosage form: eye drops cream and ointment. This certification is valid upto 21-07-2015.

#### **Decision of 10<sup>th</sup> Meeting of EEC:**

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 validation of certification from the Ministry of Health Vietnam. The earlier certification has expired.

“The certification of Ministry of Health about Rohto-Mentholatum (Vietnam) Company Ltd., No. 16 VSIP, Street 5, Vietnam Singapore Industrial Park, Thuan an Town, Binh Duong Province, VIETNAM is in the field of practice of finished medicine not containing antibiotic b-Lactam in the dosage form: eye drops cream and ointment was produced by the applicant. This certification was valid from 21-07-2015, but due to misunderstanding it was written as valid upto 21-07-2015. The documents of the importer are complete.”

#### **Decision**

“Deferred till forthcoming meeting due to constraint of time”

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2. **M/s RAX Laboratories (Homoeopathic)**, was inspected and following sections were approved in 10<sup>th</sup> Meeting of EEC held on 29-04-2016. Supportive documents like layout plan and invoices were attached at 22-KM, Ferozpur Road, Guju Mata, Lahore which created confusion and issuance of enlistment certificate on Form-6 was with held.

S. No.	Name and address of the Manufacturer	Name of approved Sections
1.	<b>M/s Rax Laboratories (Homoeopathic)</b> , 14 Allama Iqbal Road, Lahore.	<b>Homoeopathic Sections: -</b> 1. Oral liquid 2. Tablet 3. Capsule 4. Semisolid (Ointment/ Cream)

But it was revealed that the firm submitted application at 14 Allama Iqbal Road, Lahore. It was verified from Mr. Adnan Faisal Saim, DDC (QC-1 & II), who stated vide his letter dated 11-05-2016 & Diary No. 254 dated 12/05/2016 as under:

“In compliance to letter No.F.1-628/2016-DDC (Health & OTC) the panel visited the manufacturing site situated at 21 KM Ferozpur Road, Lahore. The firm has also submitted the request in this regard (copy enclosed). Submitted for consideration please.”

### **Decision**

“Deferred till forthcoming meeting due to constraint of time”

3. **M/s. Z-JANS Pharmaceuticals (Pvt.) Ltd.**, Following sections of M/s Z-Jans were approved.

S. No.	Name and address of the Manufacturer	Name of approved Sections
1.	<b>M/s. Z-JANS Pharmaceuticals (Pvt.) Ltd.</b> , 148-A, Hayatabad Industrial Estate, Peshawar.	1. Tablet 2. Capsule 3. Sachet <b>4. Ointment/ Cream</b> 5. Topical liquids

The enlistment certificate on Form-6 was issued but **ointment and cream section** was with held as the same was not available in the layout plan submitted by the firm.

### **Decision**

“Deferred till forthcoming meeting due to constraint of time”

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### **B. DRUG MANUFACTURING LICENSE INSTEAD OF DIETARY SUPPLEMENT MANUFACTURER REGISTRATION.**

**M/s. AAN NUTRA CARE PVT LTD**, 611, 612 & 613 Caesar Tower Opp: Ayesha Bawani School Main Shahrah-e-Faisal, Karachi, Pakistan. (Agent of M/s. Robinson Pharma, Inc. 3330 South Harbor Boulevard, Santa Ana, California 92704, U.S.A)

#### **Decision**

Agenda item No. 5 (1 & 2) is deferred for further evaluation on the basis of Principal decision given below.

#### **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 Nutraceutical 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 entrained for enlistment.
5. Only applicants having Sole Agency Agreement for the product with Principal Manufacturer / Legal Owner abroad will be entrained.
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.

The firm has provided FDA registration, products specific Agency Agreement and free sale certificates as per decision of the EEC.

#### **Decision**

**“Deferred till forthcoming meeting due to constraint of time”**

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### **C. 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 has 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 has 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 company's 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 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 in 9<sup>th</sup> Meeting of EEC:**

The Enlistment Evaluation Committee considered the application/ record and evaluated the application for enlistment of the above firms and granted approval for Enlistment Certificates

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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.

Now the firm has submitted attested copy of order of Chief Commissioner, Islamabad Court in case of Irfan Nazir V/s TIENS through MD TIENS, Islamabad in respect of Writ Petition No. 3222/2015. The Chief Commissioner announced decision on 4<sup>th</sup> May, 2016 and reproduced decision of EEC dated 4<sup>th</sup> April, 2016. He further announced as under:

**“I am of the considered opinion that DRAP is the relevant body to evaluate and enlist the products being sold by the TIENS. Therefore, TIENS is directed to approach the DRAP for same and enlistment certificate, if obtained be also furnished to this Court. Meanwhile in order to operate provisionally pending its enlistment, NOC may also be obtained from DRAP. The instant complaint is accordingly disposed off.”**

**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 clarified and undertake that;

1. That from the commencement of our business in Pakistan, we have never been involved in any type of unethical / illegal activity related to the sales of our food supplements (which are currently being categorized by DRAP as alternative medicine under Health and OTC Division).
2. That all our products are imported with full compliance to Pakistan customs and tariffs regulatory requirements, including paying the relevant tariffs and taxes.
3. That we are an enterprise in Pakistan in lawful existence and good standing since the last 14 years, which has contributed a lot to the national exchequer of Pakistan and created jobs and other social welfares.
4. That our certain matters with SECP are pending adjudication since the last many years, yet the company continues to operate as a legal entity and has been undertaking its business in normal fashion.
5. That we are continuing to operate as a legal entity and comply with all applicable laws and regulations of Pakistan.

### **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. However this certificate would be revoked if adverse order is passed by any Court of Law against the company or the company fails to fulfill his commitments stated in the undertaking.”**



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### **ITEM: - III IMPORTED PRODUCTS WITH HELD AT PORT DUE TO NON CLEARANCE:-**

1. **M/s Merck Specialties (Private) Limited**, Head office: 4<sup>th</sup> Floor, D-7, Shaheed-e-Millat Road, P.O. Box 13021, Karachi (As agent of **M/s Hovid Berhad**, 121, Jalan Tunku, Abdul REHman, 30010 IPOH, Perak, **MALAYSIA**) **Enlistment No. 0069**

S. No.	Brand Name & composition (List of ingredients with strength)	Common name of ingredients	Recommended conditions for use	Pack size	MRP	Decision by EEC
1.	<b>Seven Seas Cod Liver Oil Gold</b> Each softgel contains:  Cod Liver Oil (BP).....264mg	Cod Liver Oil	1. Supplement containing Vitamin A, D, and Omega 3 Fatty acids. 2. Maintenance of good health.	100 soft gel health pearls	Rs.900/-	
2.	<b>Seven Seas Ginkgo Max</b> Each tablet contains  Ginkgo Biloba extract (USP).....40mg  USP specifications	Ginkgo Biloba	i. Helps to enhance cognitive function in adults. ii. Helps to enhance memory in adults. iii. Helps to support peripheral circulation.	90 Tablets	Rs.1400/-	

2. **M/s Matrix Pharma (Pvt.) Limited**, Plot No. 12, Sector-15, Korangi Industrial Area, Karachi-74900 is Agent of **M/s ANA Bio Research and Development JSC**, Head Office: No. 22, Lot 7, Van Khe Urban, La Khe Ward, Ha Dong district, Hanoi City, **VIETNAM**. **Enlistment No. 0015**

S. No.	Brand Name & composition (List of ingredients with strength)	Common name of ingredients	Recommended conditions for use	Pack size	MRP	Decision by EEC
1.	<b>Matrix Ospor Oral Suspension</b> (Drinkable Ampoule) Each 5ml contain:  Bacillus Clausii....2 billion CFU per 5ml (sterilized water) USP / specification monograph	Bacillus Clausii	Probiotics for oral use	5ml		

3. **M/s ATCO Healthcare (Pvt.) Limited**, B-18, S.I.T.E., Karachi is Agent of **M/s Rohto-Mentholatum Australasia Pvt. Ltd.**, 12-16 Janine Street, Scoresby, Victoria 3179, **AUSTRALIA**. **Enlistment No. 00245**

S. No.	Brand Name & composition (List of ingredients with strength)	Common name of ingredients	Recommended conditions for use	Pack size	MRP	Decision by EEC
1.	<b>Deep Heat Regular Rub</b> Each Tube contain:  Methyl Salicylate (BP).12.74%/w/w Menthol Reacemic (USP)..5.88%/w/w Turpentine Oil (BP).....1.46%/w/w Eucalyptus Oil (BP).....1.96%/w/w Lanolin (BP).....0.51%/w/w PCMX (BP).....0.51%/w/w Megasperse 147AS.....29.46%/w/w Water-Deionised.....47.49%/w/w  BP/ Specification monograph	Methyl salicylate Menthol Turpentine oil Eucalyptus oil Lanolin Chloroxylenol Glyceryl stearate Water	For temporary relief of minor aches and pains of muscles and joints.	50g 100g 140g	-	

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4. **M/s Bayer Pakistan (Private) Limited, C-21, S.I.T.E., Karachi is Agent of M/s PT Bayer Indonesia, Cimanggis Plant, Jl. Raya Bogor Km 32, Depok 16416, INDONESIA (Human use). Enlistment No. 00128**

S. No.	Brand Name & composition (List of ingredients with strength)	Common name of ingredients	Recommended conditions for use	Pack size	MRP	Decision by EEC
1.	<b>REDOXON DOUBLE ACTION</b> Each tablet contain:  Vitamin C (USP).....1000mg Zinc (USP).....10mg  USP specification	Ascorbic acid Zinc citrate	1. Vitamin C and zinc supplements. 2. Antioxidant for maintenance of good health.	-	-	

### Decision

**“Deferred till forthcoming meeting due to constraint of time”**

#### ii. LIMITS OF VITAMINS AND MINERALS IN THE FOOD SUPPLEMENTS:

Recommended Dietary Allowances (RDAs) have sometimes been used by national regulatory authorities as the basis for setting safe upper levels for vitamins and minerals. However, it is important to note that the RDA and the UL are determined by two completely different conceptual approaches. There is now increasing scientific consensus that upper safe levels should be established by scientific risk assessment based on generally accepted scientific data, and that safe upper levels based on arbitrary multiples of RDAs have no scientific validity. For example, at its 2003 meeting the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) dropped any further consideration of RDA-based limits.

RDA values are set on a very similar basis from one country to another—that basis is the consensus of scientific opinion on the quantities of these nutrients needed to confidently assure the performance of recognized physiological functions related to their essentiality.

Thus, the RDA values are related to avoidance of classical nutrient deficiency signs and symptoms. Although this basis for the RDA may be appropriate for undernourished populations, the needs are different for well-nourished and over-nourished populations.

A significant fraction, such as 15 percent, of the RDA can be used appropriately to set lower limits for vitamins and minerals in supplements.

RDA-based values are not valid for judging safety because:

1. The RDA is not defined or identified to describe safety or represent a safety limit for total or supplemental intake.
2. RDA-based limits are not possible for nutrients without established RDA values. For example, no RDA has been set for lutein, lycopene, boron, and many other important substances with nutritive value. These substances have beneficial effects, but the available evidence has not been judged sufficient to identify RDAs, although that may occur in the future. Risk assessment can be used to identify appropriate safety limits for these important nutrients, whether or not an RDA has been set.
3. Arbitrary limits at or near the RDA may preclude certain benefits of some nutrients. For example, well-documented benefits of nutrient quantities above the RDA include:
  - a. Folic acid, vitamin B6 and vitamin B12 which help control plasma homocysteine concentrations. Homocysteine is not yet accepted as a recognized risk factor for heart disease, but there is an ever-increasing body of scientific evidence to

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support this finding. Supplementation with these three vitamins definitely helps control plasma concentrations of homocysteine, and is likely to be proven to reduce risk of heart disease.

b. Supplementation with 200 micrograms of selenium to diets containing about 100 micrograms has been shown in a long-term, well-conducted clinical trial to reduce the incidence of three important types of cancer. A confirmatory clinical trial is underway that, if positive, would justify a widespread public health policy to increase selenium intake in many populations. In the meantime, there is no reason to deny accurate information about the state of the current evidence and to restrict selenium supplements to the RDA.

c. Supplementation of diets containing less than 40 micrograms of chromium with additional 200 to 400 micrograms helps maintain normal blood glucose levels and minimize the signs and symptoms of type II diabetes. Clinical trials confirm the safety of up to 1,000 micrograms of supplemental chromium.

4. The imposition of RDA-based upper limits is a disproportionate restriction on supplement products, compared with conventional foods. Certain conventional foods contain many multiples of the RDA of some nutrients. For example, the natural amounts of vitamin B12 in conventional foods such as liver and some shellfish can approach 100 micrograms per 100 gram serving. The adult RDA for this vitamin is commonly set at approximately 1.4 to 2.5 micrograms. Thus, these ordinary conventional foods may contain upwards of 40 to 70 multiples of the RDA of vitamin B12. There is no known toxicity of oral vitamin B12 in humans. Thus, RDA-based upper limits are not rational, serve no useful purpose, and are a disproportionate response to any hypothetical safety concern about this vitamin.

5. Labeling, not limits, can address proper usage. Labeling can provide information on contents, benefits related to RDA or other measures of benefit, and draw attention to limits imposed on a safety basis, as identified by risk assessment.

Food and Nutrition Board, Institute of Medicine National Academies USA has defined tolerable upper intake levels of vitamins and minerals which could be used safely in the dietary supplements or food supplements. Attachment of the Board, Institute of medicine and National academies defined limits is attached herewith to be opted as reference documents for the food supplements enlistment. (Annex-\_)

### **Decision of 10<sup>th</sup> Meeting of EEC:**

**The matter was discussed and deferred for further deliberation and evaluation in the forthcoming Meeting of EEC.**

### **International Comparisons:**

**(Source Vitamin and Mineral Safety published by Council for Responsible Nutrition, 3<sup>rd</sup> Edition, 2014)**

Tolerable upper intake level (UL), of Vitamins and Minerals in Supplements defined by Council for Responsible Nutrition (CRN), US Institute of Medicine (IOM), European Commission on Safety of Food (ECSCF) or European Food Safety Authority (EFSA), and UK Expert group on Vitamins Minerals (EVM).

<b>Nutrient Vitamins and Minerals</b>	<b>CRN UL (amount/ day)</b>	<b>US IOM UL (amount/ day)</b>	<b>EC SCF/EFSA UL (amount/ day)</b>	<b>UK SVM SUL or GL (amount/ day)</b>
Vitamin A	10,000 IU (3,000 µg RAE)	10,000 IU	10,000 IU	5,000 IU
Beta Carotene	25mg non-smokers, smokers should not use.	Not determined	Not determined	7 mg supplements, smokers should not use.
Vitamin D	250 µg (10,000 IU)	100 µg (4,000 IU)	100 µg (4,000 IU)	250 µg (1,000 IU)
Vitamin E	1000mg(1600IU)	1000mg(1600IU)	300mg	540mg
Vitamin k	10mg	Not determined	Not determined	1mg
Vitamin C	2000mg	2000 mg	Not determined	1000mg
Vitamin B1 (Thiamine)	100mg	Not determined	Not determined	100mg

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Vitamin B2 (Riboflavin)	200mg	Not determined	Not determined	40mg supplement 43 mg total (GL)
Nicotinic acid	500mg	35mg	10mg	17mg
Nicotinamide	1500mg	35mg	900mg	500mg supplement 560 mg total (GL)
Pyridoxine	100mg	100mg	25mg	10mg
Folic Acid	1000µg	1000µg	1000 µg	1000 µg
Vitamin B12	3000 µg	Not determined	Not determined	2000 µg
Biotin	2500 µg	Not determined	Not determined	900 µg
Pantothenic Acid	1000mg	Not determined	Not determined	200mg supplement 210mg total (GL)

Tolerable upper intake level (UL), of Vitamins and Minerals in Supplements defined by Council for Responsible Nutrition (CRN), European Food Authority (EFSA), UK Expert group on Vitamins and Minerals (EVM), European Commission on Safety of Food (ECSCF) and US Institute of Medicine (IOM).

Nutrient Vitamins and Minerals	CRN UL (amount/ day)	US IOM UL (amount/ day)	EC SCF/EFSA UL (amount/ day)	UK SVM SUL or GL (amount/ day)
Calcium	1500mg	2500mg	2500mg	1500mg
Phosphorous	1500mg	4000mg.	not determined	250 mg supplement 2400 mg total (GL)
Magnesium	400mg	350mg	250mg	400mg supplement (GL)
Potassium	1500mg ( 500mg thrice)	Not determined	Not determined	3700 mg supplement (GL)
Boron	6mg	20mg	10mg	9.6mg (SUL)
Chromium	1000mcg	1000mcg	Not determined	10 mg (10,000 µg) total (GL)
Copper	9mg	10mg	5mg	10 mg total (SUL)
Fluoride	No ULS (UL=6 mg)	10	7mg	Not determined
Iodine	500µg	1100µg	600µg	500 µg supplement 930µg total (GL)
Iron	60mg (full stomach)	45mg (empty stomach)	Not determined	17mg supplement (GL)
Manganese	10mg	11mg	Not determined	4 mg supplement 12.2mg total (GL)
Molybdenum	350µg	2000µg	600µg	230µg food (GL)
Selenium	200 µg	400 µg	300 µg	350 µg supplement 450 µg total (SUL)
Zinc	30mg	40mg	25mg	25 mg supplement 42 mg total (SUL)

**CRN:** Council for Responsible Nutrition

**US IOM:** United States Institute of Medicine

**ECSCF:** European Commission on Safety of Food

**EFSA UL** European Food Authority (EFSA)

**GL:** Guidance Level (may apply to total or supplemental intake)

**UK EVM:** UK Expert group on Vitamins and Minerals (EVM)

**SUL:** Safe Upper Tolerable Limit

**UL:** Tolerable upper intake level

### Decision

“Deferred till forthcoming meeting due to constraint of time”

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(iii) **Request for NOC as Directed Vide Notification Dated 12-10-2015 for the Clearance of Herbal Medicine (Masti Support) for Veterinary Use. Also for Enlistment of Importer (Agent of Principle Manufacturer AHV Animal Health Division International): -**

With reference to letter received from custom authorities (copy attached) regarding NOC required for clearance of our herbal medicine Masti Support for veterinary use vide letter of DRAP dated 12-10-2015.

We have already submitted our file for enlistment of importer & product (copies are attached), we are arranging legalized documents as per your checklist received on 15<sup>th</sup> March, 2016 (copy attached) for screening of documents for enlistment of INCHEM INTERNATIONAL as importer/ agent of Principle Manufacturer AHV Animal Health Division International, we hereby submitting the deficient documents identified during initial screening of our application,

1. Copy of Letter received from custom authorities regarding NOC.
2. Copy of receiving for file submission of importer.
3. Copy of receiving for file submission of Masti Support.
4. Letter of DDC regarding checklist for screening documents for enlistment of company.
5. GMP certificate.
6. Copy NTN certificate of Inchem International.
7. Site Master File of the Principle Manufacture.
8. Name and address of Proprietor.
9. List of products intended to be imported (along with formula, pack, size and detail of primary pacing material.
10. Storage facility.
11. Attested copy of Drug Wholesale license.

### Decision

**“Deferred till forthcoming meeting due to constraint of time”**

1. **M/s Omana International**, Office No. 19, 3<sup>rd</sup> Floor, Crown Plaza, B-224, Satellite Town, Rawalpindi. (M/s Omana Group, LLC 11562 Knott Avenue, Suite 5, Garden Grove, California 92841, USA)

Enlistment No.	List of ingredients with strength	Common Name of Ingredients	Recommended use	Pack Size	Maximum Retail Price
1.	<b>Vegan Tablet</b> Vitamin A.....4000 IU Vitamin C.....5mg Vitamin D.....400 IU Thiamin.....3mg Riboflavin.....2mg Niacin.....10mg Vitamin B6.....1mg Folic Acid.....800mcg Vitamin B12.....2mcg Calcium.....250mg Iron.....27mg Iodine.....0.01mg Magnesium.....0.15mg	Vitamin A Vitamin C Vitamin D Thiamin Riboflavin Niacin Vitamin B6 Folic Acid Vitamin B12 Calcium Iron Iodine Magnesium	Nutritional Supplement	30 Tablets	795/-

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	Zinc.....0.085mg Copper.....0.15mg Manganese.....0.05mg Potassium.....0.835mg	Zinc Copper Manganese Potassium			
2.	<b>Joints Life Capsule</b> Vitamin C.....20mg Vitamin E.....20mg Manganese.....0.7mg Boron.....0.5mg Chicken Collagen Hydrolysate.....300mg Shark Cartilage.....150mg Boswellia Extract.....60mg Stinging Nettle Leaf Extract.60mg Bromelain.....50mg Turmeric Extract.....30mg	Vitamin C Vitamin E Manganese Boron Chicken Collagen Hydrolysate Shark Cartilage Boswellia Stinging Nettle Leaf Bromelain Turmeric	It protects joints  Keep people active  Useful for players and old age people	30 Capsules	1050/-
3.	<b>Vegan Plus AZ Tablet</b> Vitamin A.....5000 IU Vitamin C.....90mg Vitamin D.....400 IU Vitamin E.....30 IU Vitamin K.....25mcg Thiamin.....2.25mg Riboflavin.....2.6mg Niacin.....20mg Vitamin B6.....3mg Folic Acid.....400mcg Vitamin B12.....9mcg Calcium.....162mg Iron.....27mg Iodine.....150mcg Magnesium.....100mg Zinc.....15mg Copper.....2mg Manganese.....5mg Potassium.....30mg Biotin.....45mcg Pantothenic Acid.....10mg Phosphorous.....125mg Chromium.....25mcg Molybdenum.....25mcg Chloride.....27.2mg	Vitamin A Vitamin C Vitamin D Vitamin E Vitamin K Thiamin Riboflavin Niacin Vitamin B6 Folic Acid Vitamin B12 Calcium Iron Iodine Magnesium Zinc Copper Manganese Potassium Biotin Pantothenic Acid Phosphorous Chromium Molybdenum Chloride	Nutritional Supplement  For Vitamin and Mineral deficiency	30 Tablets	1295/-
4.	<b>Formula for Joints Tablet</b> Vitamin C.....15mg Vitamin E.....30mg Manganese.....1mg Boron.....0.75mg Glucosamine Sulphate.....375mg Chondroitin Sulfate.....25mg Boswellia Extract.....40mg Stinging Nettle Leaf Extract.40mg Bromelain.....35mg Turmeric Extract.....40mg Shark Cartilage.....10mg Noni.....10mg Methyl Sulfonyl Methane..120mg	Vitamin C Vitamin E Manganese Boron Glucosamine Sulphate Chondroitin Sulfate Boswellia Stinging Nettle Leaf Bromelain Turmeric Extract Shark Cartilage Noni Methyl Sulfonyl	It provides joints  Keep people active  Useful for players and old age people	30 Tablets	Un-Controlled

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5.	<b>Fisol</b> Natural Fish Oil.....100mg Omega 3 Fatty Acids.....300mg DHA.....120mg EPA.....180mg	Natural Fish Oil Omega 3 Fatty Acids DHA EPA	Improves Health Maintains Cholesterol level, Helps in cardiac problems	30 Capsules	Rs. 980/-
6.	<b>Res. 30</b> Vitamin B1.....1.5mg Vitamin B2.....1.7mg Vitamin B6.....2mg Calcium Carbonate.....75mg Niacine.....20mg Magnesium.....40mg	Vitamin B1 Vitamin B2 Vitamin B6 Calcium Carbonate Niacine Magnesium	Dietry Supplement  It promotes restful sleep	30 Capsules	Rs. 1190/-
7.	<b>Bone Health Booster</b> Ascorbic Acid.....6mg Cholecalciferol.....1200 IU Vitamin E.....10 IU Calcium.....1200mg Magnesium.....400mg Zinc.....15mg Copper.....2mg Manganese.....2mg Vanadium.....50mg Boron.....250mg Silicon.....25mg	Vitamin C Vitamin D Vitamin E Calcium Magnesium Zinc Copper Manganese Vanadium Boron Silicon	For Healthy bones	30 Tablets	1790/-
8.	<b>Nervix</b> Vitamin B1.....37.50mg Vitamin B2.....2.55mg Vitamin B6.....2mg Vitamin B12.....3mcg Alpha Lipoic Acid.....225mg Acetylcarnitine.....235mg Turmeric Extract.....45mg	Vitamin B1 Vitamin B2 Vitamin B6 Vitamin B12 Alpha Lipoic Acid Acetylcarnitine Turmeric	Dietry Supplement  Proper blend for the support of neuropathy	30 Capsules	Rs. 980/-
9.	<b>Fisol</b> Lepidium meyenii.....200mg Epimedium sagittatum.....60mg Proprietary blend.....490mg L-arginine HCl, Cnidium extract, Muira pauma extract (Ptychopetalum olacoids) Ashwaganda extracts (Withania somnifera), ginseng extract (Panax ginseng), Oat straw extract (Avena sativa), Saw palmetto extract (Serenoa repens) Berry, ginkgo biloba.	Macca Horney Goat Weed Proprietary blend		30 Capsules	Rs. 1995/-
10.	<b>Bone Health Plus</b> Ascorbic Acid.....6mg Cholecalciferol.....800 IU Vitamin E.....10 IU Calcium.....1000mg Magnesium.....400mg Zinc.....15mg Copper.....2mg Manganese.....2mg Boron.....250mg	Vitamin C Vitamin D Vitamin E Calcium Magnesium Zinc Copper Manganese Boron	For Healthy Bones	30 Tablets	1290/-
11.	<b>Bone Health Tablet</b> Cholecalciferol.....400 IU Calcium.....1000mg Magnesium.....400mg Zinc.....15mg	Vitamin D Calcium Magnesium Zinc	For Healthy bones	30 Tablets	790/-

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Already Form-7 issued to M/s. Brooklyn Pharmaceuticals, located at the address **687, Ground Floor, New Abadi Ali Abad, Alla Abad Road, Westridge-III, Rawalpindi - Pakistan** to be manufactured by M/s. Omana Group LLC, 11562 Knott Avenue, Suite 5, Garden Grove, California 92841 U.S.A. same overseas Principal and 5 products were approved by EEC in its 10<sup>th</sup> Meeting.

Enlistment No.	Brand Name & Composition (List of ingredients with strength)	Common Name of ingredients	Recommended use	Pack size	Decision by EEC
0039.0001	<b>Ecolin Tablet</b> <b>Each Tablet Contain:</b> Vitamin C(USP) .....6mg Cranberry Extracts(Eur.Ph)...250mg  Finished product shall conform to USP Specifications	Ascorbic acid Vaccinium macrocarpon	1.(Traditionally) used as Herbal Medicine to help prevent (recurrent) urinary tract infections (UTIs) 2. (Used as Herbal Medicine to) help(s) prevent recurrent urinary tract infections (UTIs) in women 3. Provides antioxidants for the maintenance of good health.	30 Tab/ bottle	
0039.0002	<b>CMZ-3 Tablet</b> <b>Amount as per three tablets serving:</b> Calcium(USP).....1000mg Magnesium(USP).....400mg Zinc(USP).....15mg VitaminD3(USP).....400 IU  Finished product shall conform to USP Specifications	Calcium Magnesium Oxide Zinc sulfate Cholecalciferol	1. Vitamin D3, calcium, magnesium and zinc supplement. 2. Maintenance of good health.	30 Tab/ bottle	<b>-do-</b>
0039.0003	<b>CMZ-3 Plus Tablet</b> <b>Three Tablets provide:</b> Calcium(USP).....1000mg Magnesium(USP).....400mg Zinc(USP).....15mg Vitamin D (USP).....1000IU Copper(USP).....2mg Manganese(USP).....2mg Boron(USP).....250mg Vitamin C(USP).....6mg Vitamin E(USP).....10IU  Finished product shall conform to USP Specifications	Calcium Magnesium Zinc Vitamin D Copper Manganese Boron Vitamin C Vitamin E	1. Multivitamin – multi - mineral Supplement  2. Maintenance of good health.	30 Tab/ bottle	<b>-do-</b>
0039.0004	<b>BCIP Plus Tablet</b> <b>Amount as per three tablets serving:</b> Calcium (USP).....1100mg Magnesium(USP).....400mg Zinc (USP).....15mg Vitamin D(USP).....1000 IU Vitamin C(USP).....6mg Vitamin E(USP).....10 IU Copper (USP).....2mg	Calcium carbonate Magnesium Oxide Zinc gluconate Cholecalciferol Ascorbic acid dl-alpha tocopherol Copper sulfate Manganese sulfate	1. Multivitamin – multi - mineral Supplement  2. Maintenance of good health.	30 Tab/ bottle	<b>-do-</b>



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Manganese (USP).....2mg Boron(USP).....250mcg Fish Oil concentrate (DHA/EPA) (USP).....150mg  Finished product shall conform to USP Specifications	Boroncitrate Fish Oil (DHA/EPA)			
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### **Decision**

**“Deferred till forthcoming meeting due to constraint of time”**

### **Disclaimer:**

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

**Pakistan Zindabad.**