MINUTES OF 240th MEETING OF DRUGS REGISTRATION BOARD HELD ON 07th November, 2013

240th meeting of the Registration Board was held on 07th November, 2013 in the Committee Room, Minitrsy of National Health Regulation Service & Coordination Division, Local Government Building, G-5, Islamabad. The meeting was chaired by Mr. Ghulam Rasool Dutani, Director, Pharmaceutical Evaluation & Registration Division. The meeting started with the recitation of Holy Verses. The meeting was attended by the following:-

1.	Lt General (R) Karamat Ahmed Karamat.	Member
2.	Brig (R). Dr. Muzammil Hasan Najmi, Associate Dean, Basic Sciences Division, Foundation Medical University, Rawalpindi.	Member
3.	Mr. A.Q. Javed Iqbal, Chief Pharmacist, PIMS, Islamabad.	Member
4.	Dr. Muhammad Arshad, President, Pakistan Veterinary Medical Council	Member
5.	Dr. Muhammad Khalid Khan Director Drugs Testing Laboratory Government of Khyber Pakhtoonkhwa, Peshawar.	Member
6.	Muhammad Jamil Anwar Director Drugs Testing Laboratory Government of Punjab, Lahore.	Member
7.	Dr.Amanullah Khan Director Drugs Testing Laboratory Government of Baluchistan, Quetta	Member
8.	Ms.Saima Kanwal Representative of IPO,Islamabad	Member
9.	Muhammad Israr Deputy Draftsman, Ministry of Law and Justice	Member
10.	Dr.Noor Muhammad Shah Director Medical Devices and Medicated Cosmetics, DRAP	Member
11.	Abdul Samad Khan Director, Biological Drug, DRAP	Member

12.	Dr. Obaidullah, Deputy Director General (Reg.I).	Secretary/Member

Mr.Akhter Abbas Khan (DDG R.II), Mr.Muhammad Arif (DDC R.I), Mr. Babar Khan (DDC R.III), Dr. Tariq Siddique (DDC R.IV), Ms. Tehreem Sara (DDC MDMC) and Mr. Asif Jalil (ADC MDMC) assisted Secretary of the Board with agenda.

Mr. Saeed Allawala & Mr. Khalid Muneer, Mr.Nadeem Alamgeer and Dr.M.Qasim Awan attended the meeting as observer on behalf of PPMA, Pharma Beauru and PVPMA respectively.

Item No I: Confirmation of minutes 239th meeting Registration Board.

239th meeting of Registration Board was held on 12th September, 2013 and minutes were accordingly circulated to all members through e-mail. Following 3 members forwarded their comments as follows, for consideration of registration Board:

Dr.Amanullah, Director DTL, Quetta:

The 239th DRB Meeting Minutes are confirmed, however the following observations may be considered by the Board.

- Personally i feel that during the meeting our respectable Observers may avoid to impose their decisions as they are observers so it's better that the Members of the Board may be allowed to make their decisions in the larger interest of the country.
- The observers may not be included in any inspection.
- There should be a defined policy for the selection of the members for panel inspection within a country or abroad.

Dr.M.Khalid Khan, Director DTL, Peshawar:

The minutes 239th meeting of the Registration Board were approved subject to slight amendment in few decision which were not correctly mentioned as per decision taken during meeting as under:

- Case No.11 Fast track registration M/S Shazeb Haripur. " the Board decision was by constituting panel for PSI/ evaluation of production facilities of the firm but decision reflected in minutes are not recommended / Shortcoming rectified.
- Agenda for Biological Case Miscellaneous Amson Vaccine & Pharma " the Board decision was by constituting panel for PSI/ evaluation of production facilities of the firm regarding naked vials but decision reflected in minutes are Registration Board deferred firm's request for evaluation by ECBD.
- Case No 30. the board was not satisfied with working of biological division regarding scrutinization/ evaluation process of registration applications but it was reflected as satisfied.

Mr.A.Q. Javed Iqbal, Chief pharmacist, PIMS:

1. I was just scanning through the minutes of DRB meetings and have found some concerns and observation which are as follows;

- In the 237th DRB meeting, a presentation was given by the Biological Division for the establishment of policy to clear the backlog and improve the process. The Biological Division has asked for approval of "qualified molecules" as a blanket policy and I had asked for the list of molecule to molecule evaluation substantiated with technical comments before approving any of these. No product to product evaluation sheath with the comments of the technical reviews were submitted and the minutes were approved and later on the product list was sent which categorized the products into three broad groups as follows, (reproduced here as copy attached with the minutes)

A) Recommended and Approved for advance parallel process verification and GMP inspection of bulk and/or finished product manufacturing facility for GMP and Clinical Trial Sites/ CRO for GCP and Contract Laboratory for GLP (if required/whatever the case may be) by the panel recommended by Division of Biological Evaluation and Research (DBER). Dossier on electronic format (CD) is required to finalize the examination process of the application. CTD format of ICH will be an added advantage.

B) Recommended to consider for Market Authorization/ Registration/Licensing of biological drug if applicant could provide summary of approval/ review report of any one of the ICH countries or WHO SRA and transportation/ storage practice during its supply chain. Post registration GMP inspection and critical review will be conducted within appropriate period of time by Division of Biological Evaluation and Research and its identified experts respectively.

C) Recommended and approved for advance parallel process verification and GMP inspection of both foreign facility producing bulk and domestic site intended for finished product manufacturing. If applicant and site found within the reasonable range of regulatory compliance for safety, effectiveness and quality of drugs, Clinical Trial Sites/ CRO for GCP to check the level of science based expectations and Contract Laboratory for GLP to obtain confidence on accuracy, reliability and genuineness of data will be subsequently inspected/ evaluated

accordingly. Dossier on electronic format (CD) is required to finalize the examination process of the application. CTD format of ICH will be an added advantage.

This language can cause confusion and concern in understanding the proposed molecules status and self-assumption for interpretation of this heterogeneous group. It may kindly be shared on individual molecule assessment basis. According to the minutes of ECBD (as copy attached and sent to me), there was no "molecule specific" scrutiny conducted and it was merely a "broad policy statement" as mentioned in the minutes of ECBD which read as follows,

D) "2.1.3. RECOMMENDATION FOR APPROVAL OF MARKETING AUTHORIZATION OF FINISHED BIOLOGICAL DRUGS: "

Recommendation: All applications which have gone through the rigorous review processes and already succeeded to get market authorization from the World Health Organization (WHO) defined Stringent Regulatory Authority (SRA), International Conference of Harmonization (ICH) countries are recommended for approval and will also be forwarded under default mechanism in future within shortest period of time, if applicant could:

A. Submit summary of regulatory review report and approval,

B. Submit Common Technical Documents both via CD in Electronic format and paper format

C. Manage to arrange Process Verification and Inspection of Manufacturing facility (s)

D. Demonstrate that transportation, storage, handling will not impact on predefined attributes

Note: (1) Authorization will be withdrawn by default, if any one of the SRA or ICH countries imposes any alert on its use or import at any time. Importer and registration holder will be responsible to verify the status before import of each consignment and bound to report the situation within a week to DRAP. Written approval of continuation will be reissued by the DRAP upon review of supplement information and satisfaction.

(2) Importers and registration holders will be bound to keep themselves update about GMP compliance of facility and transportation etc. In any case where violation is recorded by any regulatory agency, the same will be brought into the notice of DRAP within a week time.

Dozens of products were issued these clearance letters including some molecules with un-determined biological class like product number 163 of M/S FK Parma sublingual Interferon as is obvious that being protein in nature, the oral formulation of Interferon has never been approved by FDA, EMEA, TGA regulatory authorities. There was another oral Interferon product from Russia which was cleared without understanding the technical nature. Probiotics were also cleared without their understanding and their evaluation on any existing policy.

Surprisingly enough, the same oral interferon as mentioned above from M/S F K Pharma was declared as "Homeopathic product" by the Biological Division in the DRB 239th meeting. We should give due diligence to address these issues at the earliest. Please ask for the complete record of discussion from the technical experts to avoid any such confusion in the future

In the draft of 239th meeting, M/S Packcure Pharma Rawat, allergy vaccines was presented as recommended in the 237th DRB meeting. However, the minutes of 237th meeting put these in the further evaluation and never recommended. Please ask the concerned officer to verify the status and inform the Registration Board accordingly.

Another point of concern is the following part of the Recommendations by the Biological Divsion put forwarded in the 237th meeting were as follows,

"2.1.6. REJECTION OF APPLICATION OF BULK WHICH IS NOT BEING USED IN MANUFACTURING OF PRODUCT IN THEIR HOME COUNTRY

Recommendation: All pending applications are recommended for rejection if applicant could not prove the commercial use of bulk (Biological) and its finished product accordingly in their country of origin.

A) Discussion: The expertise, capacity and resources of DRAP are limited, so undue risk need to be avoided.

However, no case to case verification was conducted to ascertain the suitability based on this criterion.

2. The information regarding the registration or de-registration of any product should also be shared with the Chief Commissioner, Islamabad along with Health Secretaries of all the

Provinces. This will ensure traceability and facilitate the regulatory information in a timely manner across the country.

Discussion: The Board discussed observations of the members, as follows:

Dr.Amanullah, Director DTL, Quetta:

- The Board was briefed that no observer has ever been included in any inspection panel.
- For inspection of manufacturing units abroad, DRAP has revised Import Policy for drugs by Policy Board. Moreover, DRAP authority in its 8th meeting decisded as follows:
    - Directorate of Administration, Human Resource & Logistics shall prepare and maintain the complete record of foreign inspection of all officers.
    - In each panel, one officer from centre and one officer from field office shall be nominated.
    - Nominations shall be made keeping in view number of foreign inspection done by the officer in past. Prioirity must be given to those officers, who have not been nominated or who have got fewer oppertyumities in the past.
    - Each panel shall consist of one senior and one junior officer.
    - No more than four companies shall be included in one panel.
    - Initially Directors of the Directorates namely Pharmaceutical Evaluation & Registration; Biological Drugs; Medical devices & Medicated Cosmetics will propose panels for inspections of manufacturer aborad, keeping in view above criteria for further approval.
    - After the clearance of backlog, nominations shall be finalized by the Authority for further approval from Federal Government.
- The observers were informed to present point of view on the matters related to their respective association.

Dr.M.Khalid Khan, Director DTL, Peshawar:

- Page No: 149 of minutes of 239th Registration Board states that products at S.No. 8 and 9 are deferred for PSI by Director DTL, Peshawar and area FID.
- The Board deferred case of M/s Amson Vaccine & Pharma for evaluation by ECBD. Inspection of the firm will be conducted after evaluation by ECBD and consideration of registration Board.

- The members were informed that Registraion Board is not considering evaluation of registration application by Directorate of Biological Drugs. For this purpose, ECBD is constituted for expert evaluation of all cases for consideration by respective Board.

Mr.A.Q. Javed Iqbal, Chief pharmacist, PIMS:

- It was informed that Registration Board in 238th meeting decided that all products which were discussed in 237th meeting will be evaluated by ECBD and Registration Board will then consider recommendation of ECBD for further decision.
- Mr.A.Q. Javed Iqbal requested Directorate of Biological Evaluation & Registration to share the registration applications submitted for Ropegra and vaccines of M/s Pak cure, Rawat. These registration applications were handed over to Mr.A.Q. Javed Iqbal for evalution. The member will submit its report for consideration of Registration Board in its next meeting.
- Registration Board was informed that Pharmaceutical Evaluation & Registration Directorate sent copy of all registration letters to all Provincial Health Secretaries. However, the Board advised to send copy of registration letter to Chief Commissioner, Islamabad as well.

Item No:02. Scrutinization of Registration Application.

In DRAP's Act, 2012; Pharmaceutical Evaluation & Registration Directorate was established. Accordingly, Pharmaceutical Evaluation Cell has been setup and tasked with evaluation of applied registration applications. The cell and DRAP's officers developed check list for evaluation of these registration applications. The check list will serve as a guideline for filling Form-5, Form-5 A and Form-5 D for applications of registeration of drugs.

Discussion:

1. Pharmaceutical Evaluation & Registration Directorate briefed the Board that after promulgation of DRAP Act, 2012; Pharmaceutical Evaluation & Registration Directorate is reponsible for the evaluation, assessment and registration of drugs. Accordingly, Pharmaceutical Evaluation Cell has been established recently to evaluataion and assessment of registration dossiers submitted by importers / manufacturers. In order to evaluate and assess timely and in an efficient manner, a check list has been prepared. This check list will not only serve as a guideline for evaluators working in the cell but applicants will also benefit from it for correct submission of registration dossier.

2. Mr.A.Q.Javed Iqbal propsed certain ammendments in the check list as follws:

a. S.No.20; In addition to mentioned requirements, serial No, make, photopgraph and date of purchase of machines should be submitted.
b. S.No.22; photographs of persons should be submitted.
c. S.No.23; In addition to mentioned requirements, serial No, make, photopgraph and date of purchase of machines should be submitted.
d. S.No.25; data regarding test / analysis of water should be part of submission.
e. S.No.26; detail of waste management system.
f. S.No. 31; website and fax number.
g. For imported drugs:
    i. Sole agency agreement with complete detail of exporter.
    ii. Authentic clinical data / trial.

3. It was discussed that in registration applications, some points pertains to product development data, stability studies, validated method of analysis etc and the most of applicants

(local manufacturers) had probably filled these points based on their experience, as they have not yet manufactured the drug and not conducted aforementioned studies.

4. The Board was apprised that presently Registration Board grant registration to pharmaceutical manufacturers with the condition "they will comply other conditions as contained in Drug Act, 1976 and rules framed there under should be strictly adhere to". The manufacturers are bound to conduct product development, stability studies, validate method of analysis etc before sale of drug but they do not submit this data to Pharmaceutical Evaluation & Registration Directorate. Moreover, as per condition of registration most of manufacturers donot submit method of analysis to Central and Provincial Drug Testing Laboratory and master formula to Assistant Drug Controller. This sitaution creats problems particularly during analysis of drugs in Central and Provincial Drug Testing Laboratory, due to absence of validated method of analysis.

5. The Board discussed following two possibilities for consideration of pending and upcoming registration applications:

a. All applicants may be advised to manufacture trial batch of applied drug and submit product development data, stability studies, validation of method of analysis etc to Registration Board for its consideration and decision on the application.
b. The applicant may be granted registration of the applied drug, if all other requirements are complete (as per check list) except product development data, 06 months accelrated and real time stability studies and validation of method of analysis. After grant of registration, manufacturer will submit aforementioned data before sale of drug, as per following procedure:
    - Product development data, 06 months accelrated and real time stability studies and validation of method of analysis to Pharmaceutical Evaluation Cell, DRAP.
    - Validated method of analysis to Central, Provincial Drug Testing Laboratories and Drug Control & Traditional Medicine Division (Appellate laboratory).
    - Master formula containing name and quantities of active and inactive materials to concerned Assistant Drugs Controller, DRAP.

Decision:

Members, Registration Board lauded efforts done by Pharmaceutical Evaluation & Registration Directoarte in preparation of check list and approved it with ammendments as proposed by Mr.A.Q.Javed Iqbal. Mr.Nadeem Alamgeer, representative Pharma Beuru agreed to the proposal while PPMA representatives sought time for discussion withtheir members.

Registration Board approved proposal at point 5(b) of above discussion as line of action for pending applications.

Registration Board approved following check list for implemetation:

S. No.	**Contents of Form-5 & it's enclosures**	**Required Document/Data to be submitted**
1	A cover letter	Letter signed by the director/owner of the company or person specifically authorized on behalf of onwer(s)
2	Evidence of fees paid	i. Bank reciept duly endorsed by STO. ii. Fee required as per Schedule-F of Drugs Act, 1976.
3	Application type on relevent prescribed form	Form-5 (Application form for registration of a drug for local manufacture). Each page signed (original) by authorized / approved production and Quality Control Incharge.
		Form -5 A
		Form 5 D
		Form 5 E
4	Title, name and address of the applicant	i. Attested Copy of DML / Renewal of DML (In case of more than 5 years)
5	Dosage form	Complete Description of dosage form of drug e.g., i. Flim coated tablet ii. Bilayered Layered Tablet (one immediately released and other is sustained released). iii. Capsule with enteric coated pellets iv. Powder for suspension etc.
6	Brand Name of Drug Product	i. Written in capital letters ii. An undertaking that in case of resemblance / similarity, the applicant would be liable to change the brand

		name. In case of approval of drug, the brand name will be checked for resemblance / similarity.
7	The drug product name (proprietary, INN or generic name, pharmaceutical form, strength) with relevant information;	Proprietary, INN or generic name of the applied drug.
8	Strength of API per unit	Strength of applied drug.
9	Pharmacological Group	Reference document of common Pharmacological drug classification or Proposed *ATC* (anatomical-therapeutical-chemical) classification
10	Recomended clinical use Documented evidence based information (Indication, side effects, contraindications, drug-drug and drug-food interaction, overdosage, atc)	i. Evidence of approval by any competant DRA (attach copy) or ii. Authentic Reference Book
11	Proposed rout of administration	Details e.g, oral, etc
12	Proposed Dosage and administration	Detail of dosage e.g, adult, paedeatric and administration procedure, etc.
13	Proposed shelf life and storage conditions	An undertaking stating that before sale of the product; accelerated and real time stability studies of 6 months with undertaking to conduct real time stability studies up to assigned shelf life & report if any result falls outside specifications (with proposed action). The responsibility of genuineness of the data will lie with the applicant.
14	Unit price	Proposed Price & Pack size As per DRAP policy
15	International (name of drug, country where registered or sold and name of company selling the drug or having registration of drug (include supporting documents/proof of international registration)	Complete details regarding international availability specially in FDA, EMA, Health Canada, TGA & MHLW (Japan) i.e., same generic, dosage form & strength etc.
16	Brands available in Pakistan along with name of manifacturer	Complete details i.e., same generic, dosage form & strength etc.
17	Composition (actives and excipients) including statement of quantitative composition, giving the weight or measure for each active substance used in the manufacture of the dosage form	Master formulation with quantities of all the ingredients including excipients.
		Batch size
		Quantities to be used per Batch
		Source of active and inactive starting materials
		Role of inactive starting materials and the Justification of their quantities used. Before marketing of the product an undertaking of submitting data regarding Pharmaceutical deveoplemnt. The responsibility of genuineness of the data will

		lie with the applicant.
18	Outline of Manufacturing method	Evidence of approval of section / manufacturing facility of applied drug (especially in case of dedication).
		Stepwise details of manufacturing process including.
		Precautions/Control required to produce specified quantities of the drug applied for registration and demonetration of cleaning validation procedures.
		Identification & description of Critical steps which may alter the results.
		Data of tests for IPQC including weight variation, hardness, friability, water content, etc.
		Before marketing of the product an undertaking of submitting data regarding Process validation data. The responsibility of genuineness of the data will lie with the applicant.
		Expected yields.
19	Persons under whose direct supervision and control the drug is manufactured with the details i. total number of technical staff and ii. name, qualification and designation of the persons directly supervising the manufacture of the drug applied for registration and any change shall be properly documented and record maintained by the manufacturer.	Total number of technical staff in the Production area along with evidence of approval from Licensing section.
		Name, qualification and designation of the person directly supervising the manufacture of the drug applied for registration.
		SOPs / procedure to record and inform about the change of person.
20	Name of equipment that will be used in the manufacture of the drug applied for registration cGMP compliant or not	List of particular equipment used showing its model, make, serial No., and date of purchase of equipment and capacities along with their status of cGMP compliance.
21	Full description of specifications and analytical methods necessary to assure identity, strength, quality, purity and homogeneicity throughout shelf life drug product.	Specfications of active starting material(s) i.e., API (Active Pharmaceutical Ingredient)
		Specfications of inactive
		Specifications of finished product must be phamacopial (if included) otherwise submit validaion for inhouse specifications, alongwith certificate of analysis of API manufacturer. i. List of all the tests for the applied dosage form (e.g, for tablets, capsules, ointments, sterile products, etc.) ii. stepwise analytical description with authentic reference (approved by regulatory body or refernce book)

		iii. Limits with authentic reference (approved by regulatory body or refernce book)
		Details of Reference standard being used: a) Primary or b) Secondary
22	Name, qualification and designation of the persons who will be responsible for the quality control of the active raw material and finished products	i. Name, qualification and designation of the persons who will be responsible for the quality control of the active raw material and finished products. ii. Evidence of approval the persons working in qualitty control from Licensing section
23	Description of equipment to be used in for quality control of the raw material and finished product	i. List of specific equipments / instruments required for tests of applied drug. e.g., Atomic Absorption Spectrophotometer is required for analysis of minerals. ii. List of equipment used showing its model, make, serial No., and date of purchase of equipment and capacities along with their status of calibration.
24	Labelling and Prescribing information (to be mentioned on the pack/leaflet). specimen or the draft shall be submitted for the following class of drugs. i. CNS drugs ii. Drugs affecting uterine motility iii. Drugs inhibiting Hormonal production iv. Harmones and other steroidal drugs excluding preparations for external & topical use. v. Narcotic/psychotropic drugs	Prescribing information (PI), Patient Information Leaflet (PIL) and Summary of product characteristics (SmPC) as per Approved by Drug regulatory agencies or authorities of FDA, EMA, TGA, Health Canada and MHLW (Japan) for following classes of drugs. i. CNS drugs ii. Drugs affecting uterine motility iii. Drugs inhibiting Hormonal production iv. Harmones and other steroidal drugs excluding preparations for external & topical use. v. Narcotic/psychotropic drugs
	Specimen of lable to be submitted by the manufacturer at the start of production.	Undertaking to submit the specimen of label (for approval) by the manufacturer at the start of production.
25	Facility of water processing with specifications	i. Source of water. ii. Specifications iii. Data regarding test / analysis of water

26	Environmental control processing with details	i. Complete detail of HVAC under which the applied drug will be manufactured Attach data for the following parameters: Particulate matter (Mention the class of area (A, B, C, D or class 100, 10000, 100 000). Humidity, temperature, air velocity and air pressure ii. Detail of waste managemnet.
27	Last GMP report	Last / latest inspection report that should be conducted with in six months from the date of evaluation of dossier and having detailed assessment of facility in which the applied drug will be manufactured whether it is GMP compliant or not.
28	Types of container / packaging	b. Specifications (Physical & Chemical Characteristics) of the container closure system (Primary Packaging, Secodary Packaging & Associated components e.g., caliberated spoon etc.) fulfilling the compendial requirement. c. Before marketing of the product an undertaking of submitting Description of Suitability of container closure system comprising of following parameters: a. Protection of Drug b. Compatibility of Drug c. Safety of Drug d. Performance of Drug Stability studies will establish the final suitability of container closure system. The responsibility of genuineness of the data will lie with the applicant.
29	Undertaking	An undertaking by the production and quality control incharges about the correctness of contents of the dossier.
30	CD	i. Check for the CD whether given or not. ii. An Undertaking that the CD contains the same information / data as submitted by the applicant in the dossier. And that the CD is in operative condition.
31	Contact details	i. e-mail address. ii. mobile & phone no.
32	In case of Pellets	Submission of:

		i. COA ii. Stability studies iii. GMP of source of pellets.
33.	In case of XR / CR / DR / SR / MR etc.	Before marketing of the product an undertaking that they shall submit the comparative dissolution profile with the established brand and the data shall be supported by relevant documents to the DRAP which will include: a. Purchase of raw material, b. Certificate of Analysis, c. Testing protocols, d. SOPs, e. Analytical data and f. Finished Product sample.

For Imported Drug: Following additional data would be asked from the applicant.

a. Original and legalized Certificate of Pharmaceutical Product as per WHO format for applied product OR Original and legalized GMP certificate of new manufacturing site with free sale certificate from regulatory body of country of origin.
b. Sole Agency Agreement with complete contact detail of exporter.
c. Credentials / Site master file.
d. Prescribing information (PI), Patient Information Leaflet (PIL) and Summary of product characteristics (SmPC) as per Approved by Drug regulatory agencies or authorities of country of origin or FDA, EMA, TGA, Health Canada and MHLW (Japan)
e. Stability Studies conducted under the Zone IV-A conditions as per ICH / WHO guidelines.
f. Authentic Clinical Data / Clinical trials
g. Clinical justification

For New Drug molecule / Dosage form / Strength / combination Following additional data would be asked from the applicant.

a. Prescribing information (PI), Patient Information Leaflet (PIL) and Summary of product characteristics (SmPC) as per Approved by Drug regulatory agencies or authorities of country of origin or FDA, EMA, TGA, Health Canada and MHLW (Japan)
b. Stability Studies conducted under the Zone IV-A conditions as per ICH / WHO guidelines.
c. Clinical Data / Clinical trials
d. Clinical justification
e. International availability specially in FDA, EMA, Health Canada, TGA & MHLW (Japan) of same generic, dosage form & strength etc.

Checked by _____ Verified by_____

Item No: III. Standard Operating Procedures for approval of post-registration variations.

Pharmaceutical Evaluation & Registration Directorate briefed that after grant of registration, certain variations are required to be approved. The Directoarte has prepared Standard Operating Procedures for all such variations. These SOPs will serve as guideline for the applicants and will also facilitate efficient working and timely disposal of cases by the Directorate.

Decision:

Registration Board discussed SOPs and approved following SOPs for implementation.

A. Locally manufactured products:

1. **Change in excipients (inactive) including flavor/ colour**

a. Application with required fee as per relevant SRO.
b. Copy of registration letter and renewal status.
c. NOC for CRF clearance.
d. Specification of existing and proposed excipients / Flavour / Colour.
e. Document confirming that proposed expcipient / inactive is of pharmaceutical grade.
f. Data for 06 months accelerated stability studies.
g. Undertaking that real time stability studies would be continued till whole of shelf life & in case of OOS (out of specifications), the applicant will inform PE&R accordingly.
h. In case of additional flavor, Application on Form 5 with full fee will be submitted.

2. **Change of source of pellets**

a. Application with required fee as per relevant SRO.
b. Copy of registration letter and renewal status.
c. NOC for CRF clearance.
d. Real time stability studies of pellets conducted by manufacturer as per conditions of zone IV-A as per ICH guidelines (Both real time & accelerated studies).
e. Certificate of analysis of manufacturer
f. GMP certificate from regulatory authority of exporting country.
g. Undertaking that shelf life of finished product would be assigned from date of manufacturing of pellets from manufacturer.

3. Transfer of registration

i) With change in manufacturing site:

a. Application with Form-5 and required fee as per relevant SRO.
b. Copy of registration letter and renewal status.

c. NOC for CRF clearance.
d. Copy of approved section by Central Licensing Board.
e. Copy of last inspection report.
f. NOC from existing manufacturer / registration holder permitting for transfer of product.
g. Statement / undertaking that applicant do not have registration of same products. If so, it has to apply for cancellation of product.
h. Accelerated stability studies of 6 months with undertaking to conduct real time stability studies up to assigned shelf life & report if any result falls outside shelf life specifications (with proposed action).
i. Validated method of analysis, master formula and product development data

ii) Change in name / title of manufacturer (site of manufacturing remains the same)

a. Application on Form-5 with required fee as per relevant SRO.
b. Copy of registration letter and renewal status.
c. NOC for CRF clearance.
d. Approval of new name / title from CLB.
e. Undertaking that the formulation, API source & Specifications, manufacturing process, analytical test methods, release & shelf life specifications have not changed.

4. Change in storage conditions/shelf life

a. Application with required fee as per relevant SRO.
b. Copy of registration letter and renewal status.
c. NOC for CRF clearance.
d. Real time stability data.

5. Change in Prescribing Information (PI)

a. Application with required fee as per relevant SRO.
b. Copy of registration letter and renewal status.
c. NOC for CRF clearance.
d. Difference between existing and proposed information in tabulated form.
e. Justification of proposed changes.
f. Reference of prescribing information of brand leader (for me too products).
g. Copy of approval from regulatory agency / authority from country of origin for brand leader.
h. Copy of label outer pack in case of changes indication/ dose/ administration etc.

6. Change in primary packaging.

a. Application with required fee as per relevant SRO.
b. Copy of registration letter and renewal status.
c. NOC for CRF clearance.
d. Justification of proposed change.

e. Accelerated stability studies of 6 months with undertaking to conduct real time stability studies up to assigned shelf life & report if any result falls outside shelf life specifications (with proposed action).
f. Shelf life of the drug product supported with justification.

7. Change of packaging materials.

a. Application with required fee as per relevant SRO.
b. Copy of registration letter and renewal status.
c. NOC for CRF clearance.
d. Justification of proposed change.
e. Existing and proposed packaging materials.
f. Difference between existing and proposed information in tabulated form.
g. Confirmation and undertaking that proposed label complies all provisions of Drugs (Labeling & Packing) Rules, 1986.
h. An undertaking that the proposed colour scheme / label has no resemble with already registered Products. In case of resemblance, new label will be changed immediately. Moreover, no case is pending at any forum / court of law regarding this matter.
i. Dosage, administration, indication & direction for use etc. on the label be in line with that of registration / marketing authorization.

8. Registration of drug for export purpose.

a. Application on Form 5 with required fee as per relevant SRO.
b. NOC for CRF clearance.
c. Copy of approved section from CLB.
d. Copy of last inspection report.
e. An undertaking that applied registration is exclusively for export purpose and will not be sold in Pakistan.
f. If formulation / product is not registered in Pakistan, then export order from importing country.

9. Change of brand name.

a. Application with required fee as per relevant SRO (in case of similarity / resemblance with already registered drug, fee will not be required).
b. Copy of registration letter and renewal status.
c. NOC for CRF clearance.
d. Justification for proposed change.
e. Information regarding previous change of brand name since registration of drug.
f. Details (batch number, date of manufacture, quantity and stock position) regarding last batch manufactured.
g. An undertaking that the proposed names do not resemble with already registered brands. In case of resemblance/similarity with already registered drug, the applicant will be liable

to change immediately. Moreover, no case is pending at any forum / court of law regarding this matter.

10. Change in shape of tablet / color and size of capsule.

a. Application with required fee as per relevant SRO.
b. Copy of registration letter and renewal status.
c. NOC for CRF clearance.
d. Justification for proposed change.
e. Undertaking that other specification of the product would remain the same.

11. Cancellation of registration of drug on firm's request.

a. Application.
b. Copy of registration letter and renewal status.
c. NOC for CRF clearance.
d. Justification
e. List of alternatives brands available in the country.
f. An undertaking that the no case is pending at any forum / court of law regarding this product.

12. Renewal of drugs applied after due date.

a. Application with required fee as per relevant SRO.
b. Copy of registration letter and last renewal status.
c. NOC for CRF clearance.
d. Reason for not submitting renewal in time.

13. Corrigendum for correction in registration letter.

a. Application with required fee as per relevant SRO, if error is on part of firm.
b. Copy of registration letter and renewal status.
c. NOC for CRF clearance.
d. Document in support of proposed correction.

B. Imported products:

1. Change of name of manufacturer of imported drugs

a. Application with required fee as per relevant SRO.
b. Copy of registration letter and last renewal status.
c. NOC for CRF clearance.
d. Original and legalized Certificate of Pharmaceutical Product as per WHO format for new manufacturer's name OR Original and legalized GMP certificate of new manufacturing site with free sale certificate from regulatory body of country of origin.

2. Change of manufacturing site/source

a. Application on Form 5A with required fee as per relevant SRO.
b. Copy of registration letter and last renewal status.
c. NOC for CRF clearance.
d. Original and legalized Certificate of Pharmaceutical Product as per WHO format for new manufacturer's name OR Original and legalized GMP certificate of new manufacturing site with free sale certificate from regulatory body of country of origin.
e. Site master file of new manufacturing site.

3. Increase or decrease in shelf life of finished products

a. Application on Form 5A with required fee as per relevant SRO.
b. Copy of registration letter and last renewal status.
c. NOC for CRF clearance.
d. Justification for proposed change.
e. Approval of regulatory body of country of origin / Original and legalized Certificate of Pharmaceutical Product as per WHO format.
f. Stability data for Zone IV A or for respective storage condition (in case of products to be stored at 2-8 ^{0}C).

4. Transfer of registration from one importer to other importer

a. Application on Form 5A with required fee as per relevant SRO.
b. Copy of registration letter and last renewal status.
c. NOC for CRF clearance.
d. Termination letter (original) from manufacturer for previous importer.
e. Authority letter/sole agent letter (original) from manufacturer.
f. NOC from existing registration holder for transfer of registration.

5. Change of packaging materials.

a. Application with required fee as per relevant SRO.
b. Copy of registration letter and renewal status.
c. NOC for CRF clearance.
d. Justification of proposed change.
e. Existing and proposed packaging materials.
f. Difference between existing and proposed information in tabulated form.
g. Confirmation and undertaking that proposed label complies all provisions of Drugs (Labeling & Packing) Rules, 1986.
h. An undertaking that the proposed colour scheme / label has no resemble with already registered Products. In case of resemblance, new label will be changed immediately. Moreover, no case is pending at any forum / court of law regarding this matter.
i. Dosage, administration, indication & direction for use etc. on the label be in line with that of registration / marketing authorization.
j. Regulatory approval of change from country of export.

6. Change of brand name.

a. Application with required fee as per relevant SRO (in case of similarity / resemblance with already registered drug, fee will not be required).
b. Copy of registration letter and renewal status.
c. NOC for CRF clearance.
d. Justification for proposed change.
e. Information regarding previous change of brand name since registration of drug.
f. Details (batch number, date of manufacture, quantity and stock position) regarding last batch imported.
g. An undertaking that the proposed names do not resemble with already registered brands. In case of resemblance/similarity with already registered drug, the applicant will be liable to change immediately. Moreover, no case is pending at any forum / court of law regarding this matter.
h. Original and legalized Certificate of Pharmaceutical Product as per WHO format for new brand name OR Original and legalized GMP certificate of new brand name with free sale certificate from regulatory body of country of origin.

Item No:IV. Miscellaneous Cases

Registration-I

Case No: 01. Change of Brand Name.

M/s. Nawal Pharmaceuticals, Rawalpindi have requested to approve the change of brand name of their registered veterinary drug namely "Ivomek 2% Injection (Reg. No.072619)" to "Floramek 2% Injection" due to resemblance of their existing brand name "Ivomek 2% Injection (Reg. No.072619)" with their already registered veterinary drug namely "Ivomek 1% Injection (Reg. No.072618)".

The applicant has deposited the required fee Rs.20000/- (Pages 1-2/Corr) and submitted following supporting documents:-

i) Copy of registration letter.

ii) Original undertaking on stamp paper regarding resemblance of new proposed brand name.

The new proposed brand name "Floramek 2% Injection" is not similar with already registered drugs as per available record.

It is general practice as per record the firm use same brand name for their same generic with different strengths. Therefore, change of brand name in this case is not logical. The both brands belong to the same firm with two strengths.

Decsion: Registration Board did not accede request of firm, as both brands have same formulation and manufactured by same company.

Case No: 02. Request for exclusion of Urdu Finished Imported packs of Campto (Irinotecan) and Permission for laser jet local printing.

M/s. Pfizer Pakistan Limited, Karachi have requested to grant them exemption from Urdu Text on the "International Packs" and local printing of registration number and MRP through laser jet before releasing the "International packs" from their warehouse on all future consignments of their following registered imported drugs. The firm has deposited required fee Rs.10000/-:-

S. No.	Reg. No.	Name of Drugs.
1.	021128	Campto 100mg Injection. (Irinotecan hydrochloride Trihydrate).
2.	0211127	Campto 40mg Injection. (Irinotecan hydrochloride Trihydrate).

M/s. Pfizer Pakistan Limited, Karachi have submitted that Campto (Irinotecan) is an anti-cancer medicine which is manufactured under strict conditions using high biotechnological processes and is used for the treatment of conditions like Advanced Colorectal Cancer, Cervical Cancer and Non-small Cell lung Carcinoma. The product is used only by specialized oncologists practicing in leading hospitals and oncology departments. At the moment, the sale of Campto packs is limited and almost 1500 units/injections per year are being sold in Pakistan which is imported directly from their principal manufacturer M/s. Pfizer Perth Limited, Australia. Due to small order quantity, it is not easy for their principal to prepare packaging of Campto according to Pakistan Regulatory specific requirements.

M/s. Pfizer Pakistan Limited, Karachi was advised to clarify whether you can import these consignments with Registration Number and MRP before import for further processing the case. In response, M/s. Pfizer Pakistan Limited, Karachi have clarify that Campto packs are imported in very limited quantity i.e. almost 1500 injections per year. Due to very low volume and limitation of minimum order quantity their principal manufacturer M/s. Pfizer Perth Limited, Australia is unable to prepare "Country specific packs" for them. Therefore, they would like to do the following printing activity at their licensed facility of M/s. Pfizer Pakistan Limited, Karachi on the imported packs of Campto:-

> "Local printing of Registration number and MRP through laser jet before releasing of Campto from their warehouse."

They have also requested for exemption from Urdu Text on the Campto "International Packs".

Decsion: Registration Board acceded firm's request for one year only and for 1500 injections. However, firm will comply Drugs (Labeling & Packing) Rules, 1986 at their licensed premesis at B-2, S.I.T.E., Karachi before sale.

Case No: 03. Request for Change of Packaging Site of Revolade Tablets 25mg & 50mg.

M/s. GlaxoSmithKline Pakistan Limited, Karachi have requested to approve the change of packaging site of their following registered imported drug as follows:-

S. No	Reg. No	Name of Product.	Existing Manufacturing / Packaging Site.	New Manufacturing / Packaging Site.
1.	069584	Revolade Tablets 25mg. Each film coated tablet contains:- Eltrombopag olamine equivalent to 25mg Eltrombopag as Eltrombopag free acid.	M/s. Glaxo Operations UK Limited, Ware, UK.	**Manufacturing Site:** M/s. Glaxo Operations UK Limited, Ware, UK. **Packaging Site:** M/s. Glaxo Wellcome S.A., Avenida, Spain.
2.	069585	Revolade Tablets 50mg. Each film coated tablet contains:- Eltrombopag olamine equivalent to 50mg Eltrombopag as Eltrombopag free acid.	-do-	-do-

They have disclosed the reason for this change that as a Global harmonization of manufacturing and supply policy of their parent company the packaging site of the product is changed from M/s. Glaxo Operations UK Limited, Ware, UK to M/s. Glaxo Wellcome S.A., Avenida, Spain. The site is approved by EMA.

The firm has deposited fee Rs.50000x2=100000/- and submitted following supporting documents:-

i) Copy of Registration letter of Revolate 25mg & 50mg Tablets.
ii) Original legalized CPP from new Site.
iii) Supporting letter from new source (Spain).
iv) Supporting letter from existing source (UK).
v) Copy of NOC for CRF.

Registration of the drug is valid till 21-04-2014.

Decision: The Board after detailed discussion approved the change in packaging site of Revolade Tablets 25mg and Revolade Tablets 50mg from M/s. Glaxo Operations UK

Limited, Ware, UK to M/s. Glaxo Wellcome S.A., Avenida, Spain. The firm will submit Form 5A and site master file. The Board authorized its Chairman for approval of issuance of registration letter accordingly.

Case No:04: Labeling Exemption for Sutures on sachets.

M/s. B. Braun Pakistan (Pvt.) Ltd., Karachi have requested for the exemption of the labeling requirements on the sachets of their following registered imported surgical sutures as technically they are unable to furnish all the information on individual packs of sutures packed in foils. But the required information is available on the outer labels of the products:-

S. No.	Reg. No.	Name of Products.
1.	023167	Premilene Sterile Surgical Sutures.
2.	023166	Safil Sterile Surgical Sutures.
3.	070920	Monoplus Surgical Sutures.
4.	070921	Premicron Surgical Sutures.
5.	070922	Monosyn Surgical Sutures.
66.	008474	Silkam Sterile Surgical Sutures.
7.	012337	Softcat Chromic Sterile Surgical Sutures.

The firm have deposited the required fee Rs.5000x7=35000/-.

Decision: The Board after detailed deliberations decided that the firm has granted exemption from the Drugs (Labeling & Packaging) Rules, 1986 for printing information on inner most label but the firm will fulfill all the requirements of the rules on outer carton under the cellophane paper with inedible ink before import into Pakistan.

Case No: 05 REQUEST FOR THE GRANT OF EXEMPTION ON SURGICAL SUTURES.

M/s. Anwar & Sons, Rawalpindi had requested to grant them exemption from printing of Registration Number on the foils of each pack of their following registered Surgical Sutures. The firm has deposited required fee Rs.5000x6=30000/-:-

S. No.	Reg. No.	Name of Products.
1.	027304	Silk Surgical Sutures.
2.	027305	Catgut Chromic Surgical Sutures.
3.	027306	Surgicryl Surgical Sutures.
4.	027307	Catgut Plain Surgical Sutures.

5.	028439	Daclon Surgical Sutures.
6.	033190	Polypropylene Surgical Sutures.

The Name of Drug, Reg. No., MRP, Mfg. date, Expiry date, Lot No. with Manufacturer name and address along with importer name and address are printed on box. They have further comment that:-

i) Their Principal company SMI – Ag Belgium is exporting to more than sixty countries.
ii) Sutures are hundreds in sizes and imports of different sizes are in small quantity.
iii) Sutures are being used by professionals (surgeons).
vi) Other imported like Sutures J&J and B. Braun are not having Reg. No on foils also and they are enclosing here brand leader Box and foil as specimen.
v) Ministry had registered their pack of 12 foils and fixed the price for the same not for foil.

In response to our letter the firm has provide more evidence of practice of other firms regarding labeling or printing of Registration Number on foils.

The DTL and Drug Inspectors have their reservation for Reg. No. on foils in side box while their principal company SMI-Belgium can't print Reg. No. on foil, therefore, they have requested to allow wavier of printing of Reg. No. on foil in side box, while other details like product name size, and description, Lot No., Mfg and Expiry, manufacturer name and address are intact.

Decision: The Board after detailed deliberations decided that the firm has granted exemption from the Drugs (Labeling & Packaging) Rules, 1986 for printing information on inner most label but the firm will fulfill all the requirements of the rules on outer carton under the cellophane paper with inedible ink before import into Pakistan.

Case No: 06. Exemption of Labeling Information on Registered Products – Surgical Sutures.

M/s. A.M. Distributors, Karachi have requested for the exemption in labeling information (Urdu language and MRP to be printed outside through inject print) of their following registered imported surgical sutures:-

S. No.	Reg. No.	Name of Products.
1.	047507	Surgiquick Surgical Sutures.
2.	047508	Monosorb Surgical Sutures.
3.	047509	Surgilactin Surgical Sutures.
4.	028426	Surgidek (Monofilament Polyamide Sutures).
5.	028406	Surgisteel (Monofilament Brand Stainless Steel Wire Sutures).
6.	027308	Surgisorb (Absorbable Polyglycolic Acid Sutures).
7.	027309	Surgisilk (Braided Silk Sutures).
8.	027310	Surgical Catgut Chromic Sutures.
9.	018246	Surgibond Sutures.
10.	018247	Prodek Sutures.

M/s. A.M. Distributors, Karachi have submitted that these are sterile sutures / ligatures and are required to be stored in tightly closed container otherwise the product quality would be compared, so under a provision to Rule-3 (i) of the drugs labeling and packaging rules 1986, it is provided that in case of a drug packed in a strip of paper or blister of foil or in a an ampoule containing the sterile suture or ligature and such strip, foil, blister or ampoule is placed in another package, it shall be sufficient to give the information on the outer packaging containing such strip, foil, blister or ampoule. Their product is packed in a box which contains 12 foil packs and imported from U.K as a finished form; all the English requirements are mentioned in each strip while opening the box in order to inject printing is not feasible because the sterility would be compromised and there is not enough space on each sachet.

M/s. A.M. Distributors, Karachi have further submitted that sutures and ligatures are not being consumed by patients and are only utilized by the qualified surgeons and other medical

professionals depending on the demand of the individual surgeons thus URDU version is not required.

They have therefore requested in order to avoid any shortages in the market in the dire need and grant them an approval for the exemption in labeling information (Urdu language and MRP to be printed outside through inject print) so to avoid any problem at the time of import of their above said surgical sutures.

M/s. A.M. Distributors, Karachi have deposited the required fee Rs.5000x10=50000/-.

Decision: The Board after detailed deliberations decided that the firm has granted exemption from the Drugs (Labeling & Packaging) Rules, 1986 for printing information on inner most label but the firm will fulfill all the requirements of the rules on outer carton under the cellophane paper with inedible ink before import into Pakistan.

Case No: 07. Request for Change of Source of Alimta 100mg Injection (Reg. No.066174) & Alimta 500mg Injection (Reg. No.043068).

M/s. Eli Lilly Pakistan (Private) Limited, Karachi have requested to approve the change of manufacturing, packaging & labeling sites of their following registered imported drug as follows:-

S.#	Reg. No	Name of Product.	Existing Manufacturing / Packaging & Labeling Site.	New Manufacturing / Packaging & Labeling Site.
1.	066174	Alimta 100mg Injection.	**Manufacturing Site:** M/s. Eli Lilly and Company Indianapolis, Indiana, USA. **Packaging & Labeling Site:** M/s. Lilly France S.A.S. F-67640 Fegersheim France.	M/s. Eli Lilly and Company Indianapolis, IN 46285, USA.
2.	043068	Alimta 500mg Injection.	M/s. Lilly France S.A.S., France	M/s. Eli Lilly and Company Indianapolis, IN 46285, USA.

M/s. Eli Lilly Pakistan (Private) Limited, Karachi have disclosed the reason for this change that due source rationalization project and capacity constraints, their manufacturing & packaging facility at Lilly France S.A.S., F-67640 Fegersheim, France will discontinue manufacturing & packaging of Alimta 100mg 500mg Injections. Therefore, M/s. Eli Lilly and Company Indianapolis, Indiana 46285, USA will perform manufacturing, packaging and release of the products.

The firm has deposited fee Rs.50000x2=100000/- and submitted following supporting documents:-

i) Applications on Form 5-A.
ii) Original CPP from new site legalized by Pakistan.
iii) Copies of registration letters.
vi) Copy of the acknowledgement of last renewal of registration of Alimta 500mg Injection.

Decision: The Board after detailed discussion approved the change in manufacturing, packaging & labeling site of Alimta 100mg Injection and Alimta 500mg Injection from M/s. Lilly France S.A.S., F-67640 Fegersheim, France to M/s. Eli Lilly and Company Indianapolis, Indiana 46285, USA. However, firm will submit site master file and Board authorized its Chairman for issuance of registration letter accordingly.

Case No: 08. Change of brand name.

M/s. S.J. & G. Fazul Ellahie (Pvt.) Ltd., Karachi have requested to approve the change of brand name of their registered veterinary drug from **"**IMEC PLUS Injection (Reg. No.069639)" to "IMEC-SUPER Injection". As the have come to know through their marketing department that the other ivermectin combinations in the market bear the word SUPER and so it will be more beneficial for them if they change the name "IMEC PLUS" to "IMEC-SUPER".

The firm have deposited the required Rs.20, 000/- and submitted the following supporting documents:-

i) Copy of registration letter.
ii) Original Undertaking on stamp paper.

iii) Copy of NOC for CRF.

The proposed brand name is not similar as per available record.

Registration of the drug is valid.

Decision: The Board deferred the matter and advised to prepare list of all human and vetrenary drugs having words in names like super, strong etc.

Case No: 09. Change of Shelf-Life of Tasigna 150mg Capsules (Reg. No.072543) from 24 months to 36 months.

M/s. Novartis Pharma (Pakistan) Limited, Karachi have requested to approve the extension of shelf life of their registered imported drug "Tasigna 150mg Capsules (Reg. No.072543) from 24 months to 36 months. The firm have deposited required fee Rs.5000/- and submitted following supporting documents:-

i) Copy of approval of 36months shelf life of Tasigna 200mg Capsules (Reg. No.052256).
ii) Copy of registration letter of Tasigna 150mg Capsules.
iii) Original Certificate of Pharmaceutical Product (CPP) issued by EMA.
iv) Copy of approval issued by Swissmedic.
v) Summary and conclusions.
vi) Registration stability report.
vii) Registration stability report – Data table.

Firm has also provided the copy of NOC for CRF.

As per practice in vogue the views of following experts regarding extension of shelf live of the product has been obtained:-

S. No.	Name of Expert.	Opinion
1.	Prof. Dr. Zafar Iqbal, Chairman, Department of Pharmacy, University of Peshawar.	Recommended
2.	Dr. Farzana Chowdhary, Director, Institute of Pharmaceutical Sciences, University of Veterinary & Animal Sciences, Lahore.	Since one strength (200mg) of the same drug has been allowed the extension in shelf life there would be no point to hold it back for a weaker strength (150mg). However, as the entire stability data provided by the firm is based on the studies performed in the country of origin it would be appropriate that while permitting the extension in shelf-life the firm be required to also conduct stability studies within Pakistan so as to re-affirm this increased duration the local conditions.
3.	Dr. Taufeeq-ur-Rehman, Assistant Professor, Quaid-e-Azam University, Islamabad.	The study data supports the application for extension of shelf life from 24 months to 36 months in Zone IV so extension in shelf life may be granted for Tasigna (Nilotinib) 150mg capsules packed in Duplex blister of PVC/PVDC with Aluminum packing. The drug is already available in Pakistan with 24 months shelf life. As no change is proposed in formulation/packaging so it is suggested that firm may be asked to submit the analysis report of previously supplied batches in Pakistan beyond 24 months up to 36 months.

Decision: The Board after detailed discussion and avialble stability data for Zone IV approved the increase in shelf life of Tasigna 150mg Capsules (Reg. No.072543) from 24 months to 36 months.

Case No: 10. CHANGE OF BRAND NAMES OF THE REGISTERED PRODUCTS AND CHANGE OF ADDRESS OF THE MANUFACTURER.

M/s. Sind Medical Stores, Karachi have requested to approve the change of product name from generic to brand names as per the global strategy of their principal i.e. M/s. DemeTECH Corporation, USA and change of address of the manufacturer from M/s. DemeTECH Corporation, 3530 NW 115 Ave, Miami, FL, 33178, USA to M/s. DemeTECH Corporation, 14175 NW 60th Ave., Miami Lakes, FL, 33014, USA of their following registered imported surgical sutures as mentioned against each:-

S#	Reg. No.	Old Generic Names.	New Brand Names.
1.	069557	DemeTech Polypropylene Nonabsorbable Surgical Sutures.	DemeLENE
2.	069558	DemeTech Rapid (PGR) Absorbable Surgical Sutures.	DemeQUICK
3.	069559	DemeTech Chromic Catgut Absorbable Surgical Sutures.	DemeGUT
4.	069560	DemeTech Surgical Stainless Steel Nonabsorbable Sutures.	DemeSTEEL
5.	069561	DemeTech Polyglycolic Acid (PGA) Absorbable Surgical Sutures.	DemeSORB
6.	069562	DemeTech Silk Nonabsorbable Surgical Sutures.	DemeSILK

The firm have deposited required fee Rs.100000x 6 =600000/- and submitted following supporting documents:-

i) Original Agency Agreement Certification by US Commercial Services, Islamabad for the Exclusive Authorization Letter to M/s. Sind Medical Stores, Karachi from M/s. DemeTECH Corporation, USA for their products.

ii) Original Notarized (Florida Notary Assn. Inc) NOC / TO WHOM IT MAY CONCERN" about the change of products name by their principal.

iii) Notarized (Florida Notary Assn. Inc) copy of US FDA FSC with the new brand names of the products.
iv) Notarized (Florida Notary Assn. Inc) copy of CE certificate.
v) Notarized (Florida Notary Assn. Inc) copy of ISO certificate.
vi) Copy of Product Registration Certificate.
vii) Original undertaking on stamp paper.
viii) Original US-FDA Free Sale Certificate.
ix) Principal company authorization letter in favour of M/s. Sind Medical Stores, Karachi for applying the said change to the DRAP on behalf of the principal.
x) Principal company announcement letter for change of address.
xi) FSC with the new address issued by US FDA duly notarized.
xii) ISO with the new address of the principal company.
xiii) CE Certificate with the new address of the principal company.

As per available record the proposed brand names has no resemblance with already registered drugs. Registration of the products is valid.

As firm has provided relevant US-FDA approval for products at S. Nos. 1, 3, 5 & 6, so request of the firm for change of products name from generic to brand names and change of address of the manufacturer from M/s. DemeTECH Corporation, 3530 NW 115 Ave, Miami, FL, 33178, USA to M/s. DemeTECH Corporation, 14175 NW 60th Ave., Miami Lakes, FL, 33014, USA may be considered for approval please.

Decision: The Board after detailed discussion approved the change in manufacturing site of following products from M/s. DemeTECH Corporation, USA and change of address of the manufacturer from M/s. DemeTECH Corporation, 3530 NW 115 Ave, Miami, FL, 33178, USA to M/s. DemeTECH Corporation, 14175 NW 60th Ave., Miami Lakes, FL, 33014, USA. The Board advised firm to submit revised Form 5A and site master file and authorized its Chairman for issuanace of letter accordingly. The Board also approved the change of brand names of these products from generic to Band as approved by country of origin.

S#	Reg. No.	Old Generic Names.	New Brand Names.
1.	069557	DemeTech Polypropylene Nonabsorbable Surgical Sutures.	DemeLENE
2.	069559	DemeTech Chromic Catgut Absorbable Surgical Sutures.	DemeGUT
3.	069561	DemeTech Polyglycolic Acid (PGA) Absorbable Surgical Sutures.	DemeSORB
4.	069562	DemeTech Silk Nonabsorbable Surgical Sutures.	DemeSILK

Registration Board deferred and advised the applicant to clarify the status of rest of products from USFDA for further necessary action.

Case No: 11. CHANGE OF FORMULATION OF ALREADY APPROVED VETERINARY DRUGS.

M/s. Attabak Pharmaceuticals, Islamabad have requested for change of formulation of their already approved veterinary drugs by the Drug Registration Board in its 237th meeting held on 26-02-2013. The registration letters of the drugs have not been issued so far due to new formulation. Now the firm has requested for change of formulation as per already approved drugs:-

S.No.	Existing Formulation.	New Formulation.
1.	Lorfen Oral Liquid Each ml contains:- **Florfenicol ……..101mg**	Lorfen Oral Liquid Each 100ml contains:- **Florfenicol……10g** **Colistin Sulphate…….50 MIU**
2.	Doxyman Water Soluble Powder Each 1000gm contains:- Doxycycline HCl…...200g Tylosin tartrate ……..100g **Amantadine HCl …….45g**	Doxyman Water Soluble Powder Each 1000gm contains:- Doxycycline HCl …. 200gm Tylosin Tartrate ……100gm **Amantadine …… …..50gm**
3.	IVO-JS Injection Each ml contains:- **Ivermectin ……11mg**	IVO-S Injection Each ml contains:- **Ivermectin ……20mg** **Vitamin –A……80,000 I.U** **Vitamin-D3……40,000 I.U** **Vitamin-E……..20mg**
4.	IVO-Super Injection Each ml contains:- **Ivermectin ……15mg**	IVO-Super Injection Each 100ml contains:- **Ivermectin ……. 1gm** **Vitamin A ……..2500,000 I.U** **Vitamin D3 …….. 375000 I.U** **Vitamin E ……. 2.5gm**
5.	Sulfatrim Powder Each 100g contains:- **Sulfadiazine Sodium…42g** **Trimethoprim…….8g**	Sulfatrim Powder Each 1000gm contains:- **Florfenicol…….150gm** **Oxytetracycline…….150gm**
6.	OXY Plus Injection Each ml contains:- **Oxytetracycline HCI.51mg**	OXY Plus Injection Each ml contains:- **Oxytetracycline (as Hcl)… 200mg**
7.	Sulfabak Injection Each 100ml contains:- **Sulphadimidine Sodium.(B.P vet)...33.34%**	Sulfabak Injection Each 100ml contains:- **Enrofloxacin…….100mg**

The firm has submitted the new dossier with the changed formulation. Submitted for consideration of the Drug Registration Board.

Decision: The Board after detailed discussion and deliberations from the veterinary expert and member Law decided that the firm has changed the composition of their products i.e generics are changed therefore it will be treated as new application and did not acceded the request of the firm except for the following in which only minor quantity of one active ingredient is revised as per already registered products. Same is practiced by the Board in previous meetings.

1.	**Doxyman Water Soluble Powder** **Each 1000gm contains:-** **Doxycycline HCl…...200g** **Tylosin tartrate ……..100g** **Amantadine HCl …….45g**	**Doxyman Water Soluble Powder** **Each 1000gm contains:-** **Doxycycline HCl …. 200gm** **Tylosin Tartrate ……100gm** **Amantadine …… …..50gm**

The Board decided to get expert opinion of previous formulations as decided. However, if applicant is interested in new formulations, then new fee will be charged accordingly.

Case No: 12 Deferred Drugs For Therapeutic Justification For Formulation/ Change Of Formulation Of Already Approved Veterinary Drugs.

Drug Registration Board in its 237th meeting dated 26-02-2013 defer under mentioned drugs due to therapeutic justification for formulation. M/s. Attabak Pharmaceuticals, Islamabad has requested for change of formulation of their already approved Me-too veterinary drugs.

S.No.	Existing Formulation.	New Formulation.
1.	FNO Mix Water Soluble Powder Each gm contains:- Neomycin sulphate…..150mg **Oxytetracycline HCl ...150mg** **Florfenicol ……. 100mg**	FNO Mix Water Soluble Powder Each gm contains: - Neomycin Sulfate…….150mg **Oxytetracycline Hcl…...300mg** **Florfenicol…….300m**g
2.	Doxylo-S Powder Each 1000gm contain Doxycycline HCl ……...200g Tylosin tartrate ……..100g **Dihydrostreptomycin ....35g** Bromhexine HCl ……...5g	Doxylo-S Powder Each 1000g contains:- Doxycycline HCl ….200g Tylosin Tartrate …...100g **Colistin Sulphate…..500MIU** **Amantadine HCl …..40g** Bromhexine HCl …..5g
3.	Tylobrom-S Powder Each 1000gm contains:- Doxycycline HCl ……..200g Tylosin tartrate ……...100g **Dihydrostreptomycin ….25g** **Bromhexine HCl …… 5g**	Tylobrom-S Powder Each 1000gm contains:- Doxycline Hydrochloride... 200gm Tylosin Tartrate……..….. .100gm **Colistin Sulphate…….....500 MIU**
4.	Doxytil-S Powder Each 1000gm contain	Doxytil-S Powder Each 1000gm contains:-

	Doxycycline HCl ……200g Tylosin tartrate ……100g **Dihydrostreptomycin …30g** **Bromhexine HCl ……5g**	Doxycyline Hcl ……....200gm Tylosin Tartrate ……..….100gm **Colistin Slphate ……..480 MIU** **Bromohexine Hcl …….3gm**
5.	Spiradox-T Water Soluble Powder Each 1000g contains:- **Doxycycline HCI……..200g** **Tylosin Tartrate…….100g** **Spiramycin adipate……25g** **Bromhexine HCI……...5g**	Spiradox-T Water Soluble Powder Each 100gm contains:- **Oxytetracycline Hcl…..6000mg** **Spiramycin Adipate...8,000,000 IU** **Bromhexine Hcl……..150mg**
6	Lincosol Powder Each 100gm powder contains:- Lincomycin HCI……..…..5g **Spectinomycin HCI……..….5g** **Amoxicillin trihydrate…….10g** **Bromhexine HCI……1.0g**	Lincosol Powder Each 100gm contains:- Lincomycin as Hcl ….. 5gm **Spectinomycin as Hcl ...10gm** **Amantadine Hcl……...3gm**

The firm has submitted the new dossier with the changed formulation Submitted for consideration of the Drug Registration Board.

Decision: The Board after detailed discussion and deliberations from the veterinary expert and member Law decided that the firm has changed the composition of their products i.e generics are changed therefore it will be treated as new application and did not acceed request of the firm. However, if applicant is interested in new formulations, then new fee will be charged accordingly.

Registration-II

Case No:14. Cancellation & Suspension of DML by Central Licensing Board.

Central Licensing Board has taken decisions in its 232nd meeting held on 29th & 30th July, 2013 as per following details:-

S. No.	Name of firm(s)	Case	Decision of CLB
1.	M/s Macquins International, Karachi	Renewal of DML	The Board took serious notice of the casual attitude of the management of the firm in submitting / completing the application for renewal of DML despite notifying them twice and decided to **reject the application for renewal of DML of the firm** In light of decision of CLB the DML has become invalid with immediate effect and refrain from production of pharmaceuticals / drugs registered in favour of firm with immediate effect
2.	M/s Brand Pharma International, Karachi	Non compliance of conditions of DML / cGMP	The Board unanimously decided to **suspend the DML No.000684 (Formulation) of the firm for a period of six months**, as the firm had contravened the conditions of DML and due to non compliance of

			cGMP under Schedule B of drugs (L,R &A) Rules 1976 and failed to appear before the Board in spite of five show cause notices / opportunities of personal hearing given to the firm.

Decsion: Keeping in view decisions of Central Licesing Board, Registration Board decided to show cause notices to both firms for cancellation of their registrered drugs.

Case No:15. Use of packaging materials with old address- Personal Hearing thereof

Registration Board in 239th meeting deferred request of M/s Novartis Pharma (Pakistan) Ltd, West Wharf, Karachi for blocking of previous address and printing of new address of M/s CSH Pharmaceuticals, Lahore for following products and advised firm to present samples of all drugs with blocked old address and printed new address for its consideration.

S. No.	Reg. No.	Name of drug(s)	Quantity	Value in rupees
1.	031354	Amoxi-Clav Injection 1.2gm	980,273	116,652,463
2.	031355	Amoxi-Clav 375mg Tablet	743,492	52,044,426
3.	031356	Amoxi-Clav 625mg Tablet	2,554,843	196,722,880
4.	031357	Amoxi-Clav 1gm Tablet	417,131	43,798,734
5.	031353	Amoxi-Clav Injection 600mg	72,000	6,847,920
6.	031358	Amoxi-Clav 156.5mg/5ml Dry Suspension 60ml	732,132	51,351,738
7.	031358	Amoxi-Clav 156.5mg/5ml Dry Suspension 100ml	69,048	6,503,631
8.	031359	Amoxi-Clav 312.5mg/5ml Dry Suspension 60ml	921,024	83,500,036
9.	031359	Amoxi-Clav 312.5mg/5ml Dry Suspension100ml	90,000	12,136,500
		Total	6,579,942	569,558,329

Representatives of M/s Novartis Pharma (Pakistan) Ltd, West Wharf, Karachi have been called with samples of drugs for presentation of samples.

Decision: Representatives of M/s Novartis Pharma, Karachi appeared befor the Board and presented samples of above drugs with blocked old address and address of new manufacturer was injeckt printed. Members of the Board observed that firm has not blocked address in proper / quality mannerand it was erased on rubbing and thus will creat doubt about the quality of product in market. Keeping in view aforementioned situation, Registration Board did not accede request of the firm.

Case No:16. Kalimate 5gm Sachet-Maple Pharmaceuticals, Karachi.

Registration Board in 218th meeting deferred following registration application of M/s Maple Pharmaceuticals (Pvt.) Ltd, Karachi for expert opinion and inspection of manufacturing abroad.

S. No	Name of drug(s) & Composition	Proposed Pack size	Demanded Price
1	Kalimate 5gm Sachet Each 1gm sachet contains:- Calcium Polystyrene Sulfonate…… 1gm (Agent for circulatory organs) (Import in bulk from M/s Kowa Company Ltd, Japan and repacked locally)	7's	Rs.453.054

Registration Board in 228th meeting considered views of following experts and after detailed discussion advised firm to conduct local clinical trials for the product. Accordingly firm was advised to coordinate with R&D section for clinical trials.

Abdul Latif Sheikh, Consultant, Department of Pharmacy Services, AKUH, Karachi	**Syed Ather Hussain,** Head of Nephrology, Agha Khan University Hospital, Karachi	**Prof.Dr. S.M.Abbass**, Department of Nephrology, Abbasi Shaheed Hospital, Nazimabad No.5, Karachi
Ca-Polystyrene Sulfonate is an ion exchange resin that is primarily prescribed in the treatment of hyperkalemia. It removes the potassium by exchanging calcium ions in the intestine and is requally effective in hyperkalemia associated with pathological conditions such as renal failure and that in drug induced hyperkalemia. It is utilized in a form of cocktail with the Regualr insulin and Ca-Gluconate for life threatening hyperkalemia. The usual adult dose is 15g 1-4 times a day PO and 30-50 g q6h rectally. While in pediatrics, the oral dose is 1 g/kg q6h either PO or rectal. This generally well tolerated with main side effects related to electrolyte abnormality, constipation, nausea/vomiting are seen. The products launch in Pakistan is a much needed step as currently there is no registered product in the local market till date which can be used in the serious conditions listed above.	Kalimate is calcium based cationic resin to be used for hyperkalemia. The mode of action is to have calcium absorption in exchange of potassium within the gastrointestinal tract. The study included about 75 patients with 63 being on dialysis and 12 non-dialysis CKD patients, out of these only 47 dialysis and 12 non-dialysis CKD patients actually participated in the study. Among the non-dialysis patients several of the patients had inconsistencies in the study. Among the non-dialysis patients several of the patients has inconsistencies in collecting data on blood pressures and weights, so they were not included in final analysis. Only about 30 of total were included in the final analysis. In the statistical analysis the study does not mention about what was the proposed sample size and how it was designed, what was the objective of the study. This makes it difficult to evaluate the results of the study. The results of the study show a drop in serum potassium levels with no significant rise in serum calcium. There was a drop in	Not received

The registration of this product in Pakistani market is endorsed, moreover it is highly suggested that it to be registered on fast track for the benefit of the patients.	serum phosphate level also which could be due to calcium binding phosphate in the intestine but same drop also was seen when sodium resin was used. The dose of the Kalimate was also very variable. There is no mentioned about constipation/ increased GI motility which is another concern with these resins. Even though the mechanism of the proposed drug looks promising and efficacy from the provided data shows comparable efficacy, safety and quality to currently available sodium resin but the number to treat (patients/subjects) in the study are very small to asses all these parameters. The provided study seems more applicable to assess efficacy of Kalimate. To evaluate safety and quality/ effectiveness compared to currently used sodium resin, we need to include more patients and properly divide in different study proups (ESRD on dialysis and or CKD).	

The firm conducted clinical trails at The Kidney Centre under supervision of Dr. Asim Ahmed, Dean & Chief Nephrologist and assisted by Dr. Kiran Nasir, Consultant Nephrologist in Kidney Center. Report of trial was also submitted to Assistant Drugs Controller (CT), Ministry of Health. Firm has also submitted that trials about Kalimate has also been published in medical journal published in Indonesia. This product has already been acknowledged in Korea, Philippines, Japan, Thailand, Taiwan, Malaysia and Indonesia.

Registration Board in 237 meeting discussed clinical trial data submitted by the firm and decided that Prof. Dr. Zafar Iqbal and Prof. Dr. Maqsood Ahmad, member, Registration Board will evaluate clinical trial data and authorized its Chairman to decide the case in light of recommendation of experts. Both experts presented their reports as follows:

Prof. Dr. Zafar Iqbal	**Prof. Dr. Maqsood Ahmad**
• Clinical trial conducted shows good results and trials have been conducted in Pakistan that shows the efficacy and safety of drug. Therefore, according to the data provided, drug is beneficial for patients and may be registered in	• This study was conducted on hypothesis that sodium resin can worsen the volume overload in patients of chronic kidney disease where as calcium polystyrene is devoid of this effect. These results were unable to prove this hypothesis because both drugs were unable to show any significant effect on serum electrolyte levels of calcium, phosphorus, and sodium and no significant change was

Pakistan. **Conclusion:** • The drug is registered in Japan and some other Asian countries and also found in B P 2012. The registration of drug may please be allowed with strict labeling conditions and warning for patients. The clinical trial (provided) in Pakistan showed the safety and efficacy of drug and will be beneficial to patients.	observed on weight of patients who were under clinical investigation. • On basis of above results, it was wrongly concluded that calcium polystyrene can be preferred over polystyrene sodium. • These results reported that calcium polystyrene when administered in a dosage 3 to 5 gm daily can cause hypomagnesaemia indicating the decrease of serum magnesium concentration which is required for the activity of a number of important enzymes, where as such effect was not observed with sodium polystyrene. • The study was conducted without getting any approval from ethical committee which is one of the basic requirements to conduct clinical trials. **Recommendation:** Kalimate 5gm cannot be registered on the basis of results presented in this clinical trial. It is further recommended that multicentered clinical trial may be conducted after the fulfillment of all basic requirements for such studies.

Decsion: Registration Board decided to get expert opinion about the product from following experts.

- Brig (R) Hakeem Khan, Quaide-e-Azam International Hospital, Islamabad.
- Prof.Dr.Ghias Butt, PIMS, Islamabad.
- Chairman, Departemt of Pharmacy, University of Balcohistan, Quetta.

Case No:17. Deferred cases:

a. Novartis Pharma (Pakistan) Ltd, Jamshoro

Registration Board in its 237th meeting deferred following products of M/s Novartis Pharma (Pakistan) Ltd, Jamshoro for reason as per mentioned in last column.

Name of Drug & Composition	Pack	Demanded MRP	Date of application, Diary No. & Form	Decision of 237th RB meeting
Voltral Emulgel 2% Each gm contains: Diclofenac diethlamine 23.2mg (Anti rheumatic anti inflammatory and analgesic)	50gm	Rs.275/-	04-01-2013 Dy.No.06 Form-5 Rs.60,000/-	Deferred for submission of application on Form5D with balance fee
CaC 1000 Plus Each 5ml contains: Calcium Carbonate……..625.00mg Magnesium hydroxide…….60.00mg Zinc Gluconate……8.70 mg Vitamin D3……..…125 IU	Not mentioned	Not mentioned	29-06-2011 Dy.No.1712 Form-5 Rs.8000/- Rs.60,000/- 09-1-2013	Deferred for submission of application on Form5D with balance fee

Now firm has provided applications on Form 5-D and remaining fee Rs.90,000/- for each product.

Decision:

Voltral Emulgel 2%: Expert opinion by Dr.Abid Farooki, PIMS, Islamabad and Head, Department of Orthopedics, Military Hospital, Rawalpindi and Agha Khan University Hospital, Karachi.

CaC 1000 Plus: Deferred till finalization of vitamin Policy by DRAP.

b. Sami Pharmaceuticals, Karachi.

Registration Board in its 238th meeting deferred following product of M/s Sami Pharmaceuticals, Karachi for reason as per mentioned in last column.

Name of Drug & Composition	Pack	Demanded MRP	Decision
Ether 150mg/2ml Injection Each 2ml contains:- α-β-Arteether ……...150mg (Anti Malarial)	3 ampoules	Rs.765.00	Deferred for i. submission of application on Form 5D and remaining fee. ii. Confirmation for approval by USFDA, EMA, regulatory body of Japan or Australia. iii. Expert opinion.

Now firm has furnished Form 5-D along with remaining fee Rs.30,000/- and submitted that above product is neither available in US nor in European region due to non-incidence of Malaria, however being marketed by many companies in India. They have further stated that α-β –Arteether is an ethyl ether derivative of artemisinin, (the active principal isolated from the Chinese medical plant, Artemisia annual) for convenient parenteral treatment of severe and complicated form of falciparum malaria. This is a racemic mixture and has added advantage over its analogues due to its increased solubility in oil medium.

Keeping in view the decreased sensitivity to commonly used antimalarials, better cure rate, low incidence of recrudescence, and shorter duration of treatment, the availability of α-β - arteether can play a vital role in the treatment of rising cases of malaria in Pakistan.

Decision: Registration Board decided to refer the matter to Director, Malraia Control Program for expert opinion. Moreover, status of product by WHO will also be checked.

c. Getz Pharma, Karachi

Registration Board in its 238th meeting deferred following product of M/s Getz Pharma, Karachi for reason as per mentioned in last column.

Name of Drug & Composition	Pack	Demanded MRP	Decision
Pronex Tablet 375mg + 20mg Tablets Each multi-layer delayed release tablet contains:- Naproxen ……375mg Esomeprazole Magnesium Trihydrate eq. to Esomeprazole…..20mg (NSAID + Proton Pump Inhibitor)	14's 20's	Rs.560.00 Rs.800.00	Deferred for i. submission of application on Form 5D and remaining fee. ii. Confirmation for approval by USFDA, EMA, regulatory body of Japan or Australia. iii. Expert opinion.
Pronex Tablet 500mg + 20mg Tablets Each multi-layer delayed release tablet contains:- Naproxen ……500mg Esomeprazole Magnesium Trihydrate eq. to Esomeprazole…..20mg (NSAID + Proton Pump Inhibitor)	14's 20's	Rs.700.00 Rs.1000.00	Deferred for i. submission of application on Form 5D and remaining fee. ii. Confirmation for approval by USFDA, EMA, regulatory body of Japan or Australia. iii. Expert opinion.

Now firm has provided applications on Form 5-D and remaining fee Rs.35,000/- for each product along with confirmation of approval by USFDA.

Decsion: Registration Board decided to get expert opinion about the product from following experts.

- **Prof.Dr. Khalid Javed, Mayo Hospital, Lahore.**
- **Prof.Dr.Abid Farooki, PIMS, Islamabad.**
- **Dr.Amanullah Khan, Director DTL, Quetta.**

d. M/s. Johnson & Johnson Pakistan, Karachi

Registration Board in 239th meeting considered following expert opinions for registration of following registration and then deferred the case for for confirmation of status of products in USFDA, EMA, TGA and regulatory body of Japan**.**

Sibelium 5mg Tablet
Each tablet contains:
Flunarizine hydrochloride…….5 mg
(Calcium Channel blocker)

Dr. Naeem Kasuri, Head of Department of Neurology, Mayo Hospital, Lahore	Dr. Ahson Nouman, Associate Professor, Department of Neurology, Services Hospital, Lahore	Dr. Mohammad Irshad, Head of Department of Neurology, Pakistan Institute of Medical Sciences, Islamabad
Awaited	I am using cap. Sibelium for Migraine prophylaxis for more than 10 years and found it effective and well tolerated in usual recommended dose of 10mg a day by majority of patient. The drug is of good quality and affordable by majority of patients.	The sibelium capsule 5mg is available for the last many years. It is used in migraine prophylaxis. We are also prescribing this medicine for our patient in out patient department of neurology. The drug is effective is mot of the patient with migraine, though the exact data is not available in our country. The drug is used all the over world and its efficacy is well established. It is also available in tablet form in many countries. It's relatively safe and has minor side effect like dizziness and somnolence. Tablet form is also available in may countries. Most of our patient also preferred tablet form of medicine. To register this medicine in tablet will be a good decision.

Now the firm has submitted that Sibelium 5mg Tablet is registered in Ireland, Switzerland, Italy, Greece, Portugal, Spain and Czech Republic.

Decsion: The Board decided to provide evidence based safety and efficacy duly supported by authentic international regulatory approvals including USFDA, erstwhile western Europe, Japan and Australia.

e. Semos Pharmaceuticals, Karachi

Registration Board in its 237th meeting deferred following products (on fast track basis) of M/s Semos Pharmaceuticals, Karachi for reason as per mentioned in last column.

Name of Drug & Composition	Pack	Demanded MRP	Date of application, Diary No. & Form	Decision
Asen Tablet Each tablet contains: Asenapine……..5 mg (Antipsychotic)	As per PRC	As per PRC	02-05-2012 Dy.No.795 Form-5 Rs.8000/- Rs.52,000/- 28-1-2013	Deferred for submission of application on form5D with balance fee
Asen Tablet Each tablet contains: Asenapine……..10 mg (Antipsychotic)	As per PRC	As per PRC	02-05-2012 Dy.No.794 Form-5 Rs.8000/- Rs.52,000/- 28-1-2013	-do-

Now firm has provided applications on Form 5-D and remaining fee Rs.90,000/- for each product.

Decsion: The Board advised firm to provide evidence based safety and efficacy duly supported by authentic international regulatory approvals including USFDA, erstwhile western Europe, Japan and Australia.

f. Zafa Pharmaceutical Laboratories (Pvt.) Ltd, (DML No.000558), Karachi

Registration Board in its 237th meeting deferred following products (on fast track basis) of M/s Zafa Pharmaceutical Laboratories (Pvt.) Ltd, (DML No.000558), Karachi for reason as per mentioned in last column.

Name of Drug & Composition	Pack	Demanded MRP	Date of application, Diary No. & Form	Decision
Dispermox 250mg Tablet Each dispersable tablet contains: Amoxicillin USP …….250 mg (Semisynthetic penicillins)	As per DPC	As per DPC	02-06-2011 Dy.No.1440 Form-5 Rs.8000/- Rs.52,000/- 25-2-2013	Deferred for submission of application on form5D with balance fee
Dispermox 500mg Tablet Each dispersable tablet contains: Amoxicillin USP …….500 mg (Semisynthetic penicillins)	As per DPC	As per DPC	02-06-2011 Dy.No.1441 Form-5 Rs.8000/- Rs.52,000/- 25-2-2013	-do-

Now firm has provided applications on Form 5-D and remaining fee Rs.90,000/- for each product. Firm has also submitted that aforementioned formulations are registered in Netherlands and France.

Decsion: Registration Board decided to get expert opinion about the product from following experts.

- **Prof.Dr. Tabish Hazir, PIMS, Islamabad.**
- **Prof.Dr.Suleman Ali, Principal, AMC, Rawalpindi.**
- **Prof.Dr.Muhammad Jamshed, Ex-Principal, University College of Pharmacy, Lahore.**

g. Sami Pharmaceuticals, Karachi

Registration Board in its 237th meeting deferred following products (on fast track basis) of M/s Sami Pharmaceuticals, Karachi for reason as per mentioned in last column.

Name of Drug & Composition	Pack	Demanded MRP	Date of application, Diary No. & Form	Decision
Xyquil DR Tablet Each delayed release tablet contains: Doxylamine Succinate …10 mg Pyridoxine HCl …….....10 mg (Anti-Emetic)	As per PRC	As per PRC	13-02-2012 Dy.No.574 Rs.8000/- Form-5 Rs.52,000/- 29-1-2013	Deferred for submission of application on form 5-D with balance fee, comparative dissolution profile with innovator brand, proof of purchase of raw material, Certificate of Analysis, testing protocols, SOPs, analytical data, finished sample and relevant documents & availability of drug in USA, EMA, Japan & Australia

Now firm has submitted that above formulation is already registered under the brand name of Envepe Tablet vide Reg. No.058492 in favour of M/s Maple Pharma, Karachi and Femiroz Tablet vide Reg. No.061026 in favour of M/s Efroze Chemical, Karachi. Firm has further submitted that as required under new Guidelines for Modified Release Tablets, they conducted comparative studies against the innovator M/s Duchesnay USA; observation revealed that quality attributes of their product and the innovator are similar, they accordingly furnished following documents for grant of registration.

- Comparative study of Dissolution Profile with that of Innovator viz M/s Duchesnay, USA
- Method of analysis of finished drug

- Proof of purchase of raw material
- Raw material certificates of analysis
- Copy of cash memo of CVS Pharmacy USA showing the purchase of Diclegis DR Tablet.

Decsion: Registration Board decided to get expert opinion about the submitted data from following experts.

- **Prof.Dr. Zafar Iqbal, Department of Pharmacy, Peshawar.**
- **Prof.Dr.Mehmood Ahmad, Department of Pharmacy, Bahawalpur.**
- **Prof.Dr.Ghulam Sarwar, Women University, Karachi.**

h. Reign Pharmaceuticals PCSIR KLC, Karachi

Registration Board in its 235th meeting deferred following product of M/s Reign Pharmaceuticals PCSIR KLC, Karachi for reason as per mentioned in last column.

Name of Drug & Composition	Pack	Demanded MRP	Remarks / Decision
Dirolyte Syrup Each 100ml contains: Sodium Chloride ……0.26g Trisodium Citrate Dihydrate…….. 0.29g Potassium Chloride……...0.15g Glucose ……1.35g (Electrolytes/ORS Liquid)	300 ml 500 ml 600 ml	Rs.11/- Per 100ml	Deferred for confirmation of terminal sterilization facility

Now firm has submitted that they have installed terminal sterilization (auto clave) in liquid ORS manufacturing section.

Decision: Registration Board advised to confirm the facility by area FID.

i. Alina Combine Pharmaceuticals, Karachi

Registration Board in its 238th meeting deferred following product of M/s Alina Combine Pharmaceuticals, Karachi for reason as per mentioned in last column.

Name of Drug & Composition	Pack	Demanded MRP	Remarks / Decision
Neurolina Injection Each 3ml contains: Cyanocobalamin.1000 mcg Pyridoxin HCl ..100 mg Thiamin HCl …100 mg	Not mentioned	Not mentioned	Deferred for providing validated method of analysis (assay)

Now firm has furnished the validated method of analysis.

Decision: Registration Board approved grant of registration of Neurolina Injection.

j. Atco Laboratories Ltd, Karachi

Registration Board in its 238th meeting deferred following product of M/s Atco Laboratories Ltd, Karachi for reason as per mentioned in last column.

Name of Drug & Composition	Pack	Demanded MRP	Remarks / Decision
Ascard Plus Forte Tablets Each film coated tablet contains:- Acetylsalicylic Acid (Aspirin) BP …….162mg Clopidogrel Bisulphate USP eq. to Clopidogrel …….75mg	10's	Rs.217.50	Deferred for confirmation of availability of Bi-layered tablets machine

Now firm has submitted that product is not a bi-layered tablet but is a tablet in tablet formulation and will be prepared like their already registered product Ascard Plus Tablet. The only difference between two products is the quantity of Aspirin.

Decision: Registration Board approved grant of registration of Ascard Plus Forte Tablets.

k. Pharmatec Pakistan, Karachi

Registration Board in its 236th meeting deferred following products (on fast track basis) of M/s Pharmatec Pakistan, Karachi for reason as per mentioned in last column.

Name of Drug & Composition	Pack	Demanded MRP	Decision
Palip XR 1.5mg Tablet Each film coated tablet contains: Paliperidone ……. 1.5 mg (Anti-Psychotic)	14's	Rs.8600/-	Extended release
Palip XR 3mg Tablet Each film coated tablet contains: Paliperidone ……. 3 mg (Anti-Psychotic)	14's	Rs.8700/-	Extended release

Now firm has provided applications on Form 5-D and remaining fee Rs.90,000/- for each product.

Decsion: The Board advised firm to provide evidence based safety and efficacy duly supported by authentic international regulatory approvals including USFDA, erstwhile western Europe, Japan and Australia. Moreover, the Board decided to get expert opinion about product from following experts:

- **Prof.Dr. Rizwan Taj, PIMS, Islamabad.**
- **Prof.Dr.Mazhar Malik, Rawal Medical College, Rawalpindi.**
- **Head, Department of Psychiatry, AKUH, Karachi.**

l. M/s Nabiqasim Industries, Karachi.

The Registration Board in 237th meeting deferred for confirmation of me too status the registration of following drug of M/s Nabiqasim Industries, Karachi

Name of Drug & Composition	Pack size	Demanded MRP	Date of application, Diary No. & Form	Decision
Co-Dep 12/25 Capsule Each capsule contains: Olanzapine ……..……12 mg Fluoxetine HCl…….……..25 mg (Anti psychotropic)	10's 14's 20's 30's	As per PRC	18-11-2011 Dy.No.372 Form-5 Rs.8000/- Rs.52,000/- 24-1-2013	Deferred for confirmation of me-too status

Later on scrutiny of registration data revealed that the above formulation is already registered for M/s Genome Pharma, Hattar under the brand name Olanco Capsuls 12/25mg, Reg. No.064014. Submitted for consideration of Registration Board.

Decision: Registration Board already deferred same formulation for review committee.

m. M/s Martin Dow Pharmaceuticals Ltd, Karachi

Registration Board in its 237th meeting deferred following products of M/s Martin Dow Pharmaceuticals, Karachi for reason as per mentioned in last column.

Name of Drug & Composition	Pack	Demanded MRP	Date of application, Diary No. & Form	Remarks / Decision
Neo Fansidar 15mg/120mg/5ml Powder for Oral Suspension Each 5ml contains: Dihydroartemisinin……...15 mg Piperaquine as phosphate……120 mg (Anti protozoal & anthelmintic)	30ml 40ml 60ml 80ml	Rs.150/- Rs.200/- Rs.300/- Rs.400/-	12-10-2012 1628 Form-5 Rs.20,000/-	Deferred for submission of application on form-5D with balance fee

Now firm has submitted that the above formulation is already registered for M/s Platinum Pharmaceuticals, Karachi under the brand name Artequine Dry Suspension, Reg. No.061467. **Decsion: The Board approved registraion of above requested formulation with advise for new brand name.**

n. M/s Tabros Pharmaceuticals Ltd, Karachi

Registration Board in its 238th meeting deferred following products of M/s Tabros Pharmaceuticals, Karachi for reason as per mentioned in last column.

Name of Drug & Composition	Pack	Demanded MRP	Remarks / Decision
Fenastol Tablets 50mg/200mg Tablets Each cover tablet contains:- Inner Enteric coated tablet contains:- Diclofenac Sodium (Enteric coated) ..50mg Outer (cover) tablet contains:- Misoprostol …..200mcg (Anti Rheumatic)	2x10's	Rs.400.00	Deferred for confirmation of availability of Bi-layered tablets machine

Now firm has submitted that the above formulation is tablet in tablet and Federal Inspector of Drugs in inspection dated 03.04.2013 already confirmed the facility. Same was also mentioned in registration application.

Decsion: The Board approved registraion of product Fenastol Tablets 50mg/200mg Tablets.

Case No:18. Extension in contract manufacturing permission.

Following firms have applied for extension in contract manufacturing permission. Details of the case are as under:-

S. No.	Applicant	Contract manufacturer	Reg. No.	Name of drug(s) & Composition	Date of application, Diary No. & Form	Category
1.	M/s Medisure Labs, Karachi	M/s Indus Pharma, Karachi	014084	Neurocoline Injection Each 2ml contains:- Citicoline ….250mg	24-10-2013 Dy No.1671 Rs.42,000/- Rs.8000/- 29.06.2010	Import to local contract manufacturing
2.	-do-	-do-	015566	Rosiden Injection Each ml contains:- Piroxicam …..20mg	24-10-2013 Dy No.1670 Rs.42,000/- Rs.8000/- 29.06.2010	-Do-
3.	M/s Novrtis Pharma, West Wharf, Karachi	M/s Global Pharmaceuticals, Islamabad	030510	Levofin 250mg Tablets (Levofloxacin)	28-03-2013 Rs.42,000/- Rs.8000/- 14.06.2010	General products
4.	-do-	-do-	030511	Levofin 500mg Tablets (Levofloxacin)	28-03-2013 Rs.42,000/- Rs.8000/- 14.06.2010	-Do-
5.	-do-	-do-	023992	Claramed Dry Suspension (Clarithromycin)	28-03-2013 Rs.42,000/- Rs.8000/- 14.06.2010	-Do-
6.	-do-	-do-	023993	Claramed 250mg Tablets (Clarithromycin)	28-03-2013 Rs.42,000/- Rs.8000/- 14.06.2010	-Do-
7.	-do-	-do-	023994	Claramed 500mg Tablets (Clarithromycin)	28-03-2013 Rs.42,000/- Rs.8000/- 14.06.2010	-Do-
8.	-do-	-do-	054727	Acemed 100 mg Tablets (Aceclefenac)	28-03-2013 Rs.42,000/- Rs.8000/- 14.06.2010	-Do-
9.	-do-	-do-	032153	Montelo 5 mg Tablet (Montelukast)	28-03-2013 Rs.42,000/- Rs.8000/- 14.06.2010	-Do-
10.	-do-	-do-	032154	Montelo 10 mg Tablet (Montelukast)	28-03-2013 Rs.42,000/- Rs.8000/- 14.06.2010	-Do-

Decision: Registration Board decided as follows:

- Product at S.No.1&2 approved. As citicoline is under consideration by review committee, thus this approval will be subject to decision of the Board on the molecule.
- Product at S.No. 3-10 deferred as do not cover under contract manufacturing policy.

Case No:19. Notification of intent to withdraw license for oral formulations of Nizoral (Ketoconazole) tablets (Regn. No.006799).

M/s Johnson Johnson Pakistan (Pvt.) Ltd, Karachi has informed that to delist and will stop the manufacturing and distribution of Nizoral (Ketoconazole) Tablets, Reg. No. 00679, once product has expired from the market. The decision does not impact other topical formulations i.e Nizoral Cream, which will continue to be made available.

Nizoral (Ketoconazole) Tablets, Reg. No. 006799 has a positive benefit: risk profile for the restricted indications when used appropriately with a risk mitigation strategy in place, as no new safety signals have been identified. However, based on feedback received from health authorities, there are very limited interests in the indications that the company is proposing.

Decsion: The Board deferred firm's request for confirmation of international regulatory status including USFDA, EMA, Japan and Australia.

Case No: 20. Correction cases:

i. Martin Dow Pharmaceuticals, Karachi.

The Registration Board in 237th meeting approved the following registration of M/s Martin Dow Pharmaceuticals Ltd, Karachi. Later on, it has been revealed that incorrect formulation was mentioned in agenda and minutes. Now, correct formulation is submitted for consideration of Registration Board.

Existing Name & Composition	**Correct Composition**
Cal One-D Forte Suspension Each 5ml contains: Ossein Mineral complex…….400 mg Cholecalciferol…….400 IU (Combination of minerals & trace elements)	Cal One-D Forte Suspension Each 5ml contains: Vitamin D ……400 IU Ossein Mineral Complex …. 400mg Corresponding to Calcium…….. 85.59mg Phosphorous ……..39.61mg Residual Mineral Salt……. 12mg Collagen…….. 107.95mg Other proteins ……32mg Trace elements Fl, Mg, Zn, Fe, Ni, Cu.) * Corresponding to approximate 212mg

	Hydroxyapatite

Decision: The Board approved correct formulation.

ii. **PharmEvo, Karachi.**

M/s PharmEvo, Karachi has requested for correction in registration letter of their already registered drug Elezinc 20mg Tablet, Reg. No.076077. Existing and correct composition is as under:-

Existing Name & Composition	**Reg. No.**	**Correct Composition**
Elezinc 20mg Tablet Each **tablet** contains:- Zinc Sulphate monohydrate eq. to elemental zinc……20mg (USP Specifications)	076077	Elezinc 20mg Tablet Each **dispersible tablet** contains:- Zinc Sulphate monohydrate eq. to elemental zinc……20mg (USP Specifications)

Decision: The Board corrected formulation as dispersible tablet.

Case No. 21. Reference from Honorable Supreme Court

Ms. Sara Awan ADC, (Pricing) has referred to the minutes of 7th Drug Pricing Committee Meeting held on 21st August, 2013 in which HRC case No. 4740/2013 was discussed. The details are as under:-

"The Director Human Rights Cell, Supreme Court of Pakistan vide his letter dated March 01, 2013 in Human Rights case No. 4740/2013 has forwarded an order of the Chief Justice of Pakistan passed on a complaint against M/s. Florance Pharma, Kahuta Triangle, Islamabad which is marketing its product namely "Y-Zee" Injection (Ceftriaxone Sodium USP) 1gm with printed price of MRP. 321.00/1's. It was complained that the company is providing this injection @ Rs. 35.00/1's against printed of Rs. 321.00/1's. The complainant has claimed that he bought it @ Rs. 38 only in the market and he has questioned why there was a difference of Rs. 283/- between printed price and market price".

Under the direction of Honourable Supreme Court, the Pricing Section asked the company to justify its case. After several reminders, M/s. Flourance Pharma, Islamabad replied as below:-

"Y-Zee Injection 1gm is manufactured by us on the system of contract manufacturing on behalf of Sarco Laboratories, Multan. We only charge contract manufacturing charges. We have never sold this injection to any chemist/store at Rs. 38/- per injection. We do our best to follow rules and regulations. The stock when manufactured is dispatched to the authorized distribution of Sarco Laboratories, who in return executes its marketing".

According to pricing section the company has violated SRO. 1103(I)/2006, and has forwarded the decision of DPC as under:-

"The DPC decided to refer the case to Registration Board for de-registration of the product".

It is submitted that the validity of registration permission was expired on 31-05-2013. The firm has applied for the extension in permission which was deferred in 238th meeting of the Registration Board due to non-submission of data about grant of registration of product, transfer registration and remaining fee of Rs. 8000/-. Hence the firm cannot manufacture the drug until the permission is extended.

Decsion: Pharmaceutical Evaluation & Registration Directorate informed the Board that M/s Sarco Laboratories, Multan applied for extension in contract manufacturing of Y-Zee" Injection (Ceftriaxone Sodium USP) but the Board deferred the application due to incomplete documents. Thus presently registration of the product is in-valid. Moreover, Registrtion Board recommended that Directorate of Cost & Price may take action against violation of SRO. 1103(I)/2006 against instant manufacturer.

Case No. 22. Change of brand name-personal hearing,

M/s. Highnoon Laboratories Ltd; Lahore was severed a show cause notice vide letter dated 23-08-2013 to why the registration of the "Aerotec (Salbutamol Sodium) 200 mcg Capsule" (Reg.No. 044593) may not be cancelled/suspended since they were failed to comply with the (ix)th condition of registration as appeared on Registration Certificate due to similarity of brand name "Aerotec (Diclofenac Sodium + Misoprostol) Tablet" (Reg.No. 040159) of M/s. Rasco Pharma, Lahore. They were directed to reply within 07 days and they can request for personal hearing in forthcoming meeting of Registration Board.

Now M/s. Highnoon Laboratories Ltd; Lahore has submitted a detailed reply and in conclusion they have requested to give them an opportunity of personal hearing to satisfy regarding their reservations spelled out in the show cause notice.

Meanwhile Mr. Syed Zia Hasnain, FID (Alternate Drugs), Lahore has informed that he had appeared in Civil Court, Lahore on 14-10-2013, in Civil Suit filed by M/s. Highnoon Laboratories, (Pvt.) Ltd; Lahore pertaining to brand name "Aerotec (Salbutamol Sodium) 200 mcg Capsule" (Reg.No. 044593).

Decsion: Representatives of firm (Ms.Irum Naila and Harron Dugal Advocate) appeared before the Board and provided courts,s orders (suit No.303/2013, Senior Civil Judge, Lahore) dated 05.10.2013 stating that defendents are hereby directed to be referained from causing any hinderance in manufacturing of Aerotec products. Expert members reviewed the court order and decided to postpone the cases till decision by the court.

Item No. V. Quality Control cases

Case No. 01: DEFERRED CASES

a) MANUFACTURE AND SALE OF SPURIOUS, SUBSTANDARD AND ADULTERATED ISOTAB TABLETS BY M/S. EFROZE CHEMICAL INDUSTRIES KARACHI.

In January, 2012 on receipt of reports of number of deaths / serious reaction in large number of patients, receiving medicines from the Punjab Institute of Cardiology, the than Drug Control Administration and Government of Punjab initiated investigation to find out facts the case. Subsequently a foreign laboratory reported contamination of antimalarial drug "Pyrimethamine" in samples of Isotab tablets of M/s Efroze Chemical Industries, sent by the Punjab Government. Since at that time the subject of "Drugs and Medicines" was devolved to the provinces under 18th Amendment, therefore, the Drug Control Administration at Federal level could not process the matter further.

The Punjab Government, however, initiated its own independent investigation during this period. An FIR, against M/s Efroze Pharmaceuticals, Karachi, was lodged by Punjab Government and a Judicial Commission, headed by Judge of High Court, had also been set up by them for carrying out detail investigation of the case.

The Provincial Quality Control Board, Punjab, later, vide its order dated 01-02-2012, reported that the samples of Tablet Isotab-20 Batch No. J-093, manufactured by M/s Efroze Chemical industries (Pvt) Ltd., Karachi, drawn by Drug Inspector, Data Ganj Bakhsh Town Lahore, (from stocks of the medicines retrieved from the patients (who received free medicines from PIC Lahore), were declared to be adulterated with "Pyrimethamine", by the Government Analyst, Drug Testing Laboratory, Punjab. The quantity of "Pyrimethamine" determined, was 46.21 mg per tab and percentage of Isosorbide-5-mononitrate (API) was declared to be 122.8%, whereas the official limit of active ingredient was 95-105%. The Provincial Quality Control Board Punjab, after considering the matter recommended cancellation of Registration of Isotab Tablet and Drug Manufacturing License of M/s Efroze Chemical Industries, Karachi vides its ordered dated 01-02-2012.

The recommendations regarding cancellation of Drug Manufacturing License was taken up by Central Licensing Board in its 231st meeting held on 30-01-2013, wherein the Board, suspended Tablet Section of Efroze Pharma and ordered to launch prosecution against the

responsible persons of the firm. The Board further recommended to the Registration Board for the cancellation of registration of Isotab Tablet.

The Drug Registration Board in its 237th meeting held on 26-02-2013 considered the matter and took following decisions.

i) Registration of Isotab Tablet is suspended for one year.

ii) Show Cause Notice to be issued to the Firm(for cancellation of Drug Registration)

iii) The case be evaluated/investigated by an Expert Committee to be constituted by the Chairman, Policy Board

As per above decisions of the Board, the following actions were taken.

a. Firm has been issued Show Cause Notices dated 09-04-2013
b. Registration of Isotab Tablets has been suspended vide letter dated 22nd March, 2013
c. A seven member committee headed by Prof. Dr. Tahir S. Shamsi of National Institute of Blood Disease and Bone Marrow Transplant, has been constituted vide letter dated 08-03-2013 to evaluate the case in detail and give its comprehensive report and recommendations with in seven days. The CLB in its 232nd meeting directed that the Committee may be asked to finalize its report on top priority basis preferably with in week's time.

During proceeding of the case in 239th meeting, the Board was informed that report of the above mentioned Committee has been received recently wherein, the Committee, as per its TOR, has evaluated report of Defective Drugs Inquiry Tribunal, recommendation of PQCB Punjab, investigation of area of FID Karachi and Inspection/investigation reports of National and International Agencies. The Committee also inspected the firm for assessing the GMP compliance status. The report of the Committee also discussed the actions taken by Federal and Provincial Authorities against M/s Efroze Chemical Industry and its finding related to GMP status of the firm. A copy of the report was given to the all members for their comments. It was also brought to the notice of the Board that the Appellate Board, before which M/s Efroze Chemical Industries also filed an appeal against suspension of their Tablet Section by CLB in the same case, allowed manufacturing in Tablet Section on limited scale under strict monitoring. M/s Efroze Chemical Industry was also called for personal hearing before the Board with

reference to the Show Cause Notice issued for cancellation of registration of Isotab Tablet. However, no one appeared before the Board on behalf of the firm. The Board decided to defer the case till next meeting in order to provide final opportunity of personal hearing to M/s Efroze Chemical Industry, Karachi, failing which an ex-parte decision shall be taken. In the mean time, the members may also study the report of the Committee and come up with their recommendations/views in next meeting.

Discussion:

The Board was briefed about background of the case as under:-

i. In January, 2012, on receipt of reports of number of deaths / serious reaction in large number of patients, receiving medicines from the Punjab Institute of Cardiology, the than Drug Control Administration and Government of Punjab initiated investigation to find out facts the case. Subsequently a foreign laboratory reported contamination of antimalarial drug "Pyrimethamine" in samples of Isotab tablets of M/s Efroze Chemical Industries, sent by the Punjab Government. Since, at that time the subject of "Drugs and Medicines" was devolved to the provinces under 18th Amendment, therefore, the Drug Control Administration at Federal level could not process the matter further. The Punjab Government, however, initiated its own independent investigation during this period. An FIR, against M/s Efroze Pharmaceuticals, Karachi, was lodged by Punjab Government and a Judicial Commission, headed by Judge of High Court, had also been set up by them for carrying out detail investigation of the case.

ii. The Provincial Quality Control Board, Punjab, later, vide its order dated 01-02-2012, reported that the samples of Tablet Isotab-20 Batch No. J-093, manufactured by M/s Efroze Chemical industries (Pvt) Ltd., Karachi, drawn by Drug Inspector, Data Ganj Bakhsh Town Lahore, (from stocks of the medicines retrieved from the patients, who received free medicines from PIC Lahore), were declared to be adulterated with "Pyrimethamine", by the Government Analyst, Drug Testing Laboratory, Punjab. The quantity of "Pyrimethamine" determined, was 46.21 mg per tab and percentage of Isosorbide-5-mononitrate (API) was declared to be 122.8%, whereas the official limit of active ingredient was 95-

105%. The Provincial Quality Control Board Punjab, after considering the matter recommended cancellation of Registration of Isotab Tablet and Drug Manufacturing License of M/s Efroze Chemical Industries, Karachi vides its ordered dated 01-02-2012.

iii. The recommendations regarding cancellation of Drug Manufacturing License was taken up by Central Licensing Board (CLB) in its 231st meeting held on 30-01-2013, wherein the Board, suspended Tablet Section of Efroze Chemical Industries for one year, and ordered to launch prosecution against the responsible persons of the firm. The CLB further recommended to the Registration Board for the cancellation of registration of Isotab Tablet. The Drug Registration Board in its 237th meeting held on 26-02-2013 considered the matter and took following decisions.

iv) Registration of Isotab Tablet is suspended for one year.
v) Show Cause Notice to be issued to the Firm(for cancellation of Drug Registration)
vi) The case be evaluated/investigated by an Expert Committee to be constituted by the Chairman, Policy Board

iv As per above decisions of the Board, the following actions were taken.

d. Firm was issued Show Cause Notices dated 09-04-2013
e. Registration of Isotab Tablets was suspended vide letter dated 22nd March, 2013
f. A seven member committee headed by Prof. Dr. Tahir S. Shamsi of National Institute of Blood Disease and Bone Marrow Transplant, was constituted vide letter dated 08-03-2013 to evaluate the case in detail and give its comprehensive report and recommendations with in seven days.

v The DRB in its 238th meeting directed that the Committee may be asked to finalize its report on top priority basis preferably with in week's time.

During proceeding of the case in 239th meeting, the Board was informed that report of the above mentioned Committee has been received recently, wherein, the Committee, as per its TOR, has evaluated report of Defective Drugs Inquiry Tribunal, recommendation of PQCB Punjab, investigation of area of FID Karachi and Inspection/investigation reports of National and International Agencies. The Committee also inspected the firm for assessing the GMP compliance status. The

report of the Committee also discussed the actions taken by Federal and Provincial Authorities, against M/s Efroze Chemical Industry and its finding related to GMP status of the firm. A copy of the report was given to the all members for their comments. It was also brought to the notice of the Board, that the Appellate Board, before which M/s Efroze Chemical Industries also filed an appeal against suspension of their Tablet Section by CLB in the same case, allowed manufacturing in Tablet Section on limited scale under strict monitoring. M/s Efroze Chemical Industry was also called for personal hearing before the Board in its 239th meeting with reference to the Show Cause Notice issued for cancellation of registration of Isotab Tablet. However, no one appeared before the Board on behalf of the firm. The Board decided to defer the case till next meeting in order to provide final opportunity of personal hearing to M/s Efroze Chemical Industry, Karachi, failing which an ex-parte decision shall be taken. In the mean time, the members were requested to study the report of the Committee and come up with their recommendations/views in next meeting. M/s Eforze was again called for personal hearing with reference to the above mentioned show cause notice.

Dr. Saifullah Awan, Manager Regulatory Affairs and Mr. Imran Raja, Liason Manager, appeared on the behalf of the firm and stated that as per their understanding the registration of Isotab tablet has already been suspended and now cancellation of registration of the drug would amount to be a double jeopardy which, therefore, would not be legally valid. The Board, however, observed that suspension of registration is an administrative action, taken by the Board in order to protect public life. Moreover, the Section 27 of the Drugs Act, 1976, which prescribe penalties for violation of the any provision of the Act, does not list suspension of registration as penalty, therefore, there is no question of double jeopardy. The Board further noted that the PQCB Punjab, while recommending cancellation of registration of Isotab tablets, observed that Isotab tablet (batch No.J-093), adulterated with pyrimethamine, has resulted in death of number of patients and further, as per PQCB, Punjab's view, criminal negligence on part of the manufacturer and gross laps in GMP has claimed many lives.

<u>Decision:-</u> The Board, in view of personal hearing of firm's representative, facts and case record, decided to cancel the registration of Isotab-20 Tablets of M/s Efroz Chemical Industries, Karachi.

Case No.02. NEW CASES

Sr. No	Name of Drugs	Firm	CDL Report	Appellate Testing	Detail / Decision
1.	Macronid Infusion Batch No.105208 & 105209 (Metronidazole) File No.03-13/2013	M/s Mac & Rain Pharmaceuticals (Pvt) Ltd, Lahore	**Sub-Standard:-** Bacterial Sterility Test Does not comply Remarks:- Direct temperature shock was applied on plastic Bottles to seal the sample		• Samples drawn from Main Medical Stor Store of Children Hospital at PIMS, on 04 by FID Islamabad who also passed not t orders. • The FID, Islamabad received copies of the reports of the aforementioned samples in M he again passed Not to Dispose off order u 18(1)(i) of Drugs Act, 1976 on 21-05-2 Center, Main Medical Store and MCH a requested for extension of not to dispose off Section 18 of the Act. • The firm in response to FID's explanation l agree with the reports and stated that one Macronid Infusion (No 105208) was alre standard by DTL, Punjab and further stated t temperature shock applied on the bottle d (remarks of Federal Government A compromised the sterility of the product. • The Federal Inspector of Drugs was of the same method of seal was applied to all the o of Mecronid Infusions, sent to Central Dru and the reports of other three batches of where the thermal shock was also reported b Government Analysis, were of standard Federal Inspector of Drugs, therefore, concl firms has violated the section (23) (1) (a) Act 1976. • The case was considered by the Drug Regis in its 239th meeting wherein, Board was apparently the initial delay in processing due to devolution of the subject of Drug and the provinces in June 2011 under 18th

					Amendment which rendered the Dr Administration, at the Federal Level, non f considerable period. Even after return of th the Federal Government in 2012, the situat uncertain for quite some time for want of c various legal formalities. The inadequate ma organizational issues, particularly in pos scenario, also contributed in the delay. The alia, decided to issue the Show Cause N accused/firm. and they were called for pers before the Board • Show Cause Notice, was accordingly iss October, 2013, to accused licensee name Muhammad Mansoor Dilawar, Mr. Abdu Khawaja Mushtaq Ahmed, and Mr. Muha and they were called for personal hearing • Mr. Qazi Muhammad Matloob Khawar, Mr. Ahmed (Deputy Plant Manager), Mr. Ahte (Production Manager), Mr. Malik Aftab and appeared on behalf of the firm and reiterate mentioned stance. **Decision:-** • The Board in view of personal hearing record of the case decided as under:- i. Production of Macronied Infusion is s further orders ii. Panel GMP Inspection, with specific investigation of cause of the proble out by the following panel:- a. Chief Drug Controller Punjab. b. Area FID.
2.	Macomez 20mg Capsules Batch No.OC-062 (Omeprazole) F.No.3-24/2012-DDC-QC	M/s Macquins International, Karachi	**Sub-Standard in respect of uniformity of weight:-** Does not complies with BP 2011	**Sub- Standard:-** Dissolution Test: Determined first Stage:- Nil Determined Final Stage:- 56.83% Limit:- First Stage:- Not more than 10% of the stated amount Limit:- Final Stage:- Not less than 65% of the stated amount	• Samples drawn from manufacturer's premis 2012 by FID Karachi. • The firm challenge the CDL test report • Show Cause Notice, was issued on 22nd Octo accused licensee namely Mr. Abdul Ra Rukhsana Saeed, Mr, Najmul Hassan and they were called for personal hearing befo vide letter dated 30th October, 2013. • The Board was informed that the firm vide

				Assay of Omeprazole:- Stated:- 20mg/cap. Found:- 17.218 mg/cap Limit:- 95-105% Percentage:- **86.09%** Does not comply with B.P.2011	has requested adjournment as due to shortage could not reach Islamabad. • The Board, however, noted that the DI Mequins has already been declared invalid a in the same meeting, has decided to issue notice to the firm for cancellation/suspensio registered products due to invalid DML.. **Decision:-** • The Board in view of available record ar case decided to suspend registration 20mg capsules till further orders sub decision of the Bord with cancellation/suspension of all registratio due to invalid DML.

Case No.03: MISCELLANEOUS CASES.

Case No.1 MANUFACTURE AND SALE OF SUB-STANDARD ALOMEP 20MG CAPSULE "BATCH NO.E40, BY M/S ALSON PHARMACEUTICALS (PVT) LTD INDUSTRIAL ESTATE, HAYATABAD PESHAWAR

The Drug Registration Board in its 238the meeting held on 06-08-2013, while considering the case of Sub-Standard Alomep 20mg Capsules (B # E-40), manufactured by M/s Alson Pharma, Peshawar, observed that the firm appears to be committing GMP violations and, therefore, decided as under:-

i. Stoppage of Production of Alomep 20mg Capsules till completion of investigation by a panel of expert
ii. Panel GMP inspection by DDG (E&M) Peshawar and Director DTL, Peshawar with specific reference to determination of actual cause of the problem.
iii. Immediate recall of the sub-standard batch from market
iv Fresh sampling of the product.

2. As per decision of the Board a GMP inspection of the firm was carried out by the nominated panel on 04-10-2013. The panel observed that the capsule filling operation was done manually and the weight variation problem was caused by un- trained/inexperienced operator, which use brush to level the spansules on filling plate instate of aluminum foil. The panel recommended for hiring of an expert and experienced operator and use of aluminum foil for leveling. The panel also recommended for restoration of production of Alomep Capsules and stated that the sampling, for test/ analyst of the product, will be done thereafter.

Discussion:

Apprising background of the case, Board was informed that the Drug Registration Board, in its 238the meeting held on 06-08-2013, while considering the case of Sub-Standard Alomep 20mg Capsules (B # E-40), manufactured by M/s Alson Pharma, Peshawar, observed that the firm appears to be committing GMP violations and, therefore, decided as under:-

i. Stoppage of Production of Alomep 20mg Capsules till completion of investigation by a panel of expert
ii. Panel GMP inspection by DDG (E&M) Peshawar and Director DTL, Peshawar with specific reference to determination of actual cause of the problem.
iii. Immediate recall of the sub-standard batch from market
iv. Fresh sampling of the product.

2. As per decision of the Board, a GMP inspection of the firm was carried out by the nominated panel on 04-10-2013. The panel observed that the capsule filling operation was done manually and the weight variation problem was caused by un- trained/inexperienced operator,

which use brush to level the spansules, on filling plate, instate of aluminum foil. The panel recommended for hiring of an expert and experienced operator and use of aluminum foil for leveling. The panel also recommended for restoration of production of Alomep Capsules and stated that the sampling, for test/ analyst of the product, will be done thereafter.
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Decision:

the Board in view of the recommendation of the Panel took following decisions:-

- **i.** Resumption of Production of Alomep 20mg Capsules.
- **ii.** Warning to the firm.

CASE NO:04 MANUFACTURING ANS SALE OF SUBSTANDARD OXASYM ORAL SUSPENSION, BATCH NO. 108.OX9 M/S SYMANS PHARMACEUTICALS (PVT) LTD., LAHORE.

The samples of Oxasym Oral Suspension, Batch No. 108.OX9, Manufactured by M/s Symans Pharmaceuticals (Pvt) Ltd., Lahore, drawn by FID Lahore from manufacturer's premises, were declared sub-standard by FGA, for having **36.9 % Oxfendazol** as against the limits of 90-110%, vide test report No. 90/2013 dated 02-04-2013. Show Cause Notices, issued on 29-05-2013 to the accused namely Saleem Haider, C.E.O/MD, Muhammad Sohail, Production Incharge, Khalid Mehmood, QC Incharge and the Firm. The accused and firm were called for personal hearing before the Board in its 238th meeting held on 06-08-2013.

Dr. Syed Saleem Haider, Managing Director, appeared on the behalf of the firm raised various objection on the FGA, report. He further claimed that they have applied for appellate testing under Section 22 (5) of Drug Act 1976, with in the prescribed period of 30 days and submitted a copy of the receipt from DRAP, Lahore office in support of his claim. The Board was informed that the FID forwarded the case to the Board on 3rd May 2013, while the receipt of request of appellate testing, as furnished by the firm, was of 2nd May, 2013.

The Board Observed that apparently that FID has forwarded the case before the request of appellate testing could reach in her office and, therefore, decided to send the Board's potion of the sample of Oxasym Oral Suspension, Batch No.108. 0X9 for appellate testing, while the FID may be advised to get the product recalled till finalization of the case by the Board.

The sample was accordingly send to the Appellate Laboratories, NIH, for Appellate testing which now again declared the sample sub-standard for having **18% oxfendazol as against the limits of 90-110%.** vide test report No. 015MNHSR/2013 dated 10-10-2013. The Appellate Lab, however, mentioned the batch No .108-OXS instead of 108.OX9

Discussion:

Apprising background of the case, the Board was informed that samples of Oxasym Oral Suspension, Batch No. 108.OX9, Manufactured by M/s Symans Pharmaceuticals (Pvt) Ltd., Lahore, drawn by FID Lahore from manufacturer's premises, were declared sub-standard by FGA, for having **36.9 % Oxfendazol** as against the limits of 90-110%, vide test report No. 90/2013 dated 02-04-2013. Show Cause Notices, issued on 29-05-2013 to the accused namely Saleem Haider, C.E.O/MD, Muhammad Sohail, Production Incharge, Khalid Mehmood, QC Incharge and the Firm. The accused and firm were called for personal hearing before the Board in its 238th meeting held on 06-08-2013.Dr. Syed Saleem Haider, Managing Director, appeared on the behalf of the firm and raised various objections on the FGA, report. He further claimed that they have applied for appellate testing under Section 22 (5) of Drug Act 1976, with in the prescribed period of 30 days and submitted a copy of their request, having receipt from DRAP, Lahore office, in support of his claim. The Board was informed that the FID forwarded the case to the Board on 3rd May 2013, while the receipt of request of appellate testing, as furnished by the firm, was of 2nd May, 2013. The Board noted that apparently that FID has forwarded the case before the request of appellate testing could reach in her office and, therefore, decided to send the Board's potion of the sample of Oxasym Oral Suspension, Batch No.108. 0X9 for appellate testing, and further advised the FID to get the product recalled through the firm till finalization of the case by the Board.

The sample was accordingly send to the Appellate Laboratories, NIH, for Appellate testing, which now again declared the sample sub-standard for having **18% oxfendazol as against the limits of 90-110%.** vide test report No. 015MNHSR/2013 dated 10-10-2013. The Appellate Lab, however, mentioned the batch No .108-OXS instead of 108.OX9.

With regards, to batch No. the Board was informed that in the font, used for printing batch No. on the label, 9 resembles S which probably led to this confusion in the CDL report

which mentioned the batch No. as 108-OX9. The batch no. on Form 3 (Intimation to person from whom samples is taken by FID) and Form 4 (Memorandum to Government Analyst by FID) the batch no. is mentioned as 108.OXS.which corresponds to the Appellate Lab's report. Therefore, it appears that FGA at CDL has misinterpreted S as 9 in batch No.

Decision:-

The Board in view of the available record and facts of the case decided as under:-

i. To issued fresh show cause notice to M/s Symans Pharma Lahore, on the basis of sub-standard Appellate Lab's repot.
ii. The production of Oxasym Oral Suspension shall be stopped till further orders.

CASE NO.05 MANUFACTURE AND SALE OF "SUBSTANDARD" HYDROGEN PEROXIDE SOLUTION BATCH NO. 840, BY M/S. KARACHI PHARMACEUTICAL LABORATORIES, KARACHI.

- Samples of Hydrogen Peroxide Solution Batch No.840, drawn from JPMC, Karachi on 09-07-2012 by FID Karachi-III was declare sub-standard by CDL. The firm could not provide any valid justification for non conformance of the product in question with the specifications.

- Show Cause Notices, for cancellation / suspension of registration / prosecution, were issued on 07-05-2013, and the accused Licensee namely Muhammad Saleh Memon, Mrs. Amina Mehboob Ali, Mrs. Farida Qureshi and the Firm were called for personal hearing before 238th DRB meeting held on 06-08-2013 but the case was deferred on request of the firm with directions to stop production of Hydrogen Peroxide till final decision by the Board.

- In 239th meeting of the Board held on 12-09-2013, Mr. Muhammad Shaban, Manager Quality Assurance, appeared on behalf of the firm and submitted a written reply. As per the reply, the firm claimed to have recalled and replaced the sub-standard stocks from the JPMC. The firm further pointed out that a sample of the same batch, drawn by FID from distributor of the firm, has been declared of standard Quality by CDL. The firm's representative also referred to their request for appellate testing made vide letter dated 10-09-2012, which, as per photocopy submitted by the firm, was received at DRAP Karachi office on 11-09-2012.

- With regards to the standard report of the same batch issue by the CDL, the Board noted that, the Federal Government Analyst, in this report, has stated that quality of the bottle and sharpness, visibility and colour of the labels text of the sample was different from the one declared sub-standard vide its earlier report. The Board, however, observed that appellate testing request of the firm appears to be with in time as per documents / evidence of the receipt submitted by the firm. The Board, therefore, decided as under:-

  i. Production of Hydrogen Peroxide be stopped till further orders.

  ii. The Board's portion of the sample (Hydrogen peroxide Batch No 840), drawn from JPMC ,Karachi be sent for appellate testing.

- The sample was accordingly sent to the Appellate Laboratories, which vide test report No.017-NRSD/2013, dated 31st October,2013 declared the sample Misbranded, with following description:-

  "The container and its neck was found cracked which damaged the label of the container badly, due to which particulars mentioned on the label were not clearly visible"

Discussion:

The Board was apprised background of the case as under :-

- Samples of Hydrogen Peroxide Solution Batch No.840, drawn from JPMC, Karachi on 09-07-2012 by FID Karachi-III was declare sub-standard by CDL. The firm could not provide any valid justification for non conformance of the product in question with the specifications.
- Show Cause Notices, for cancellation / suspension of registration / prosecution, were issued on 07-05-2013, and the accused Licensee namely Muhammad Saleh Memon, Mrs. Amina Mehboob Ali, Mrs. Farida Qureshi and the Firm were called for personal hearing before 238th DRB meeting held on 06-08-2013 but the case was deferred on request of the firm with directions to stop production of Hydrogen Peroxide till final decision by the Board.

- In 239th meeting of the Board held on 12-09-2013, Mr. Muhammad Shaban, Manager Quality Assurance, appeared on behalf of the firm and submitted a written reply. As per the reply, the firm claimed to have recalled and replaced the sub-standard stocks from the JPMC. The firm further pointed out that a sample of the same batch, drawn by FID from distributor of the firm, has been declared of standard Quality by CDL. The firm's representative also referred to their request for appellate testing made vide letter dated 10-09-2012, which, as per photocopy submitted by the firm, was received at DRAP, Karachi office on 11-09-2012.

- With regards to the standard report of the same batch issue by the CDL, the Board noted that, the Federal Government Analyst, in this report, has stated that quality of the bottle and sharpness, visibility and colour of the labels text of the sample was different from the one declared sub-standard vide its earlier report. The Board, however, observed that appellate testing request of the firm appears to be with in time as per documents / evidence of the receipt submitted by the firm. The Board, therefore, decided as under:-

  j. Production of Hydrogen Peroxide be stopped till further orders.
  iii. The Board's portion of the sample (Hydrogen peroxide Batch No 840), drawn from JPMC, Karachi be sent for appellate testing.

- The sample was accordingly sent to the Appellate Laboratories, which vide test report No.017-NRSD/2013, dated 31st October,2013 declared the sample Misbranded, with following description:-

  > "The container and its neck was found cracked which damaged the label of the container badly, due to which particulars mentioned on the label were not clearly visible"

Decision:-

The Board in view of the available record and fact of the case decided as under:-

i. Resumption of Production of Hydrogern Peroxide Solution.
ii. Warning to the firm.
iii. Panel GMP inspection by following panel.
   a. DDG (E&M) Karachi.
   b. Area FID.

CASE NO.06 DEATHS INCIDENCES AT LAHORE AND GUJRANWALA AREA ALLEGEDLY ASSOCIATED WITH CONSUMPTION OF COUGH SYRUPS UTILIZING SUB-STANDARD DEXTROMETHORPHAN RAW MATERIAL – RE-CONSTITUTION OF INVESTIGATION COMMITTEE

The recommendations of PQCB Punjab regarding the cases of manufacturing of cough syrups by M/s Reko Pharmacal & Ethical Lab Lahore, by utilizing substandard Dextromethorphan raw material, was considered by Central Licensing and Drug Registration Boards and following decisions were taken:-

A. The Central Licensing Board in its 231st Meeting held on 30-01-2013 decided as under:-

i. Import of any raw material / drug form M/s Konduskar India is banned forthwith.

ii. WHO Pakistan may be approached with the request to take up the matter with the Indian authorities through WHO India.

iii. Suspension of License of Oral Liquid / Syrup Section of M/s Reko Pharmaceuticals for one year or till completion of investigation and decision by the competent forum, whichever is earlier.

iv. Suspension of License of Oral Liquid / Syrup Section of M/s Ethical Labs for one year or till completion of investigation and decision by the competent forum, whichever is earlier.

v. Recommendations to the Drug Registration Board for Cancellation of Registration of Tyno SF Syrup of M/s Reko Pharmaceuticals and Dextromethorphan Cough Syrup and Cocil Syrup of M/s Ethical Labs

vi. Detail panel GMP inspection of the M/s Reko Pharmaceuticals and M/s Ethical Labs

The Board further decided to take up the matter again after completion of investigation by the relevant quarters

The Drug Registration Board in its 237th meeting held on 26-02-2013 took following decisions:-

i. While endorsing the ban on import from M/s Konduskar India, the Board recommended for also involving trade bodies and diplomatic channels for taking up the matter with the Indian authorities.

ii. Ministry of Commerce may be approached with the recommendation that a cautious approach made may be adopted for granting Most Favored Nation (MFN) status to the India in view of the substandard imports.

iii. A committee with following composition is constituted to thoroughly investigate the matter and submit its finding and recommendations to the Board on priority basis.

   a. Representative from DRAP
   b. Representative from the Government of Punjab
   c. Two Experts in Pharmaceutical Sciences
   d. Any other co-optive member the committee may require

iv. Suspension of registration of Tyno SF Cough Syrup of M/s Reko Pharmacal till completion of investigation and decision by the competent forum.

v. Suspension of registration of Dextromethorphan Cough Syrup and Cocil Syrup of M/s Ethical Labs till completion of investigation and decision by the competent forum.

In light of the above decisions, the CEO, DRAP vide letter dated 20-03-2013 constituted following Committee in order to investigate / study the tragic incidents allegedly associated with consumption of cough syrups, manufactured by M/s Reko Pharmacal and Ethical Pharma Lahore, by:-

i. Mr. Sultan Ghani, Former Director Health Canada
ii. Syed Shahid Nasir, Ex-Member, Central Licensing Board, Ministry of Health
iii. Prof. Dr. Mahmood Ahmed, Dean, Faculty of Pharmacy & Alternate Medicine, Islamia University, Bahawalpur.
iv. Dr. Mohammad S Iqbal, Professor, Department of Chemistry, Forman Christian College, Lahore
v. Dr. Riaz Bhatti, Head of Pharmacy, Jinnah Postgraduate Medical Graduate Centre, Karachi
vi. Prof. Dr. Muhammad Sualeh, Head of Pharmacognosy, Federal Urdu University, Karachi
vii. Dr. Iftikhar Jaffery, Sr. Director / Head of Technical Division, Pfizer, Pakistan

viii. Dr. Obaid Ali, DDC (Trg & Pharmacy Services) DRAP, Islamabad will be the Secretary / Coordinator of the investigation team / committee

However, the Committee could not show any progress after laps of over 06 months. The C.E.O, DRAP, therefore, in consultation with Chairmen, Central Licensing and Drug Registration Board's and with approval of Secretary, NHRS&C, re-constituted the Committee with the following composition:-

i. Syed Shahid Nasir,207-S, Phase–II, DHA, Lahore (Chairman)

ii. Prof. Dr. Mehmood Ahmed, Dean, Faculty of Pharmacy & Alternate Medicine, Islamia University, Bahawalpur.

iii. Prof. Dr. Muhammad S. Iqbal, Professor, Department of Chemistry, Forman Christian College, Lahore

Iv Dr. Saif-ur-Rehman Khattak,Director, CDL, Karachi

v. Prof. Dr. Muhammad Bashir, Ex-Dean, Faculty of Pharmacy, Punjab University, Currently Dean, Faculty of Pharmacy,
University of Lahore.

vi. Dr. Sheikh Akhter Hussain, DDG (E&M), DRAP, Lahore (Coordinator / Secretary Committee)

The main objective of the Committee is to investigate the matter thoroughly, taking in to account all aspects of the issue including scientific, technical, legal etc, and submit its findings with clear and candid recommendations within a period of two months positively for the consideration / decision of DRAP and the Policy Board.

Discussion:

Giving brief background of the case, the Board was informed recommendations of PQCB, Punjab regarding the cases of manufacturing of cough syrups by M/s Reko Pharmacal & Ethical Lab Lahore, by utilizing substandard Dextromethorphan raw material, was considered by Central Licensing and Drug Registration Boards and following decisions were taken:-

A. The Central Licensing Board in its 231st Meeting held on 30-01-2013 decided as under:-

vii. Import of any raw material / drug form M/s Konduskar India is banned forthwith.

viii. WHO Pakistan may be approached with the request to take up the matter with the Indian authorities through WHO India.

ix. Suspension of License of Oral Liquid / Syrup Section of M/s Reko Pharmaceuticals for one year or till completion of investigation and decision by the competent forum, whichever is earlier.

x. Suspension of License of Oral Liquid / Syrup Section of M/s Ethical Labs for one year or till completion of investigation and decision by the competent forum, whichever is earlier.

xi. Recommendations to the Drug Registration Board for Cancellation of Registration of Tyno SF Syrup of M/s Reko Pharmaceuticals and Dextromethorphan Cough Syrup and Cocil Syrup of M/s Ethical Labs

xii. Detail panel GMP inspection of the M/s Reko Pharmaceuticals and M/s Ethical Labs

The Board further decided to take up the matter again after completion of investigation by the relevant quarters

The Drug Registration Board in its 237th meeting held on 26-02-2013 took following decisions:-

vi. While endorsing the ban on import from M/s Konduskar India, the Board recommended for also involving trade bodies and diplomatic channels for taking up the matter with the Indian authorities.

vii. Ministry of Commerce may be approached with the recommendation that a cautious approach may be adopted for granting Most Favored Nation (MFN) status to the India in view of the substandard imports.

viii. A Committee with following composition is constituted to thoroughly investigate the matter and submit its finding and recommendations to the Board on priority basis.

e. Representative from DRAP
f. Representative from the Government of Punjab
g. Two Experts in Pharmaceutical Sciences
h. Any other co-optive member the committee may require

ix. Suspension of registration of Tyno SF Cough Syrup of M/s Reko Pharmacal till completion of investigation and decision by the competent forum.

x. Suspension of registration of Dextromethorphan Cough Syrup and Cocil Syrup of M/s Ethical Labs till completion of investigation and decision by the competent forum.

In light of the above decisions, the CEO, DRAP, vide letter dated 20-03-2013, constituted following Committee in order to investigate / study the tragic incidents allegedly associated with consumption of cough syrups, manufactured by M/s Reko Pharmacal and Ethical Pharma Lahore, by:-

ix. Mr. Sultan Ghani, Former Director Health Canada

x. Syed Shahid Nasir, Ex-Member, Central Licensing Board, Ministry of Health

xi. Prof. Dr. Mahmood Ahmed, Dean, Faculty of Pharmacy & Alternate Medicine, Islamia University, Bahawalpur.

xii. Dr. Mohammad S Iqbal, Professor, Department of Chemistry, Forman Christian College, Lahore

xiii. Dr. Riaz Bhatti, Head of Pharmacy, Jinnah Postgraduate Medical Graduate Centre, Karachi

xiv. Prof. Dr. Muhammad Sualeh, Head of Pharmacognosy, Federal Urdu University, Karachi
xv. Dr. Iftikhar Jaffery, Sr. Director / Head of Technical Division, Pfizer, Pakistan
xvi. Dr. Obaid Ali, DDC (Trg & Pharmacy Services) DRAP, Islamabad will be the Secretary / Coordinator of the investigation team / committee

However, the Committee could not show any progress after laps of over 06 months. The C.E.O, DRAP, therefore, in consultation with Chairmen, Central Licensing and Drug Registration Boards and with approval of Secretary, NHRS&C, re-constituted the Committee with the following composition:-

ii. Syed Shahid Nasir, (Chairman)
ii. Prof. Dr. Mehmood Ahmed, Dean, Faculty of Pharmacy & Alternate Medicine, Islamia University, Bahawalpur.
iii. Prof. Dr. Muhammad S. Iqbal, Professor, Department of Chemistry, Forman Christian College, Lahore
Iv Dr. Saif-ur-Rehman Khattak,,Director, CDL, Karachi
v. Prof. Dr. Muhammad Bashir, Ex-Dean, Faculty of Pharmacy, Punjab University, Currently Dean, Faculty of Pharmacy,
University of Lahore.
vi. Dr. Sheikh Akhter Hussain, DDG (E&M), DRAP, Lahore (Coordinator / Secretary Committee)

The main objective of the Committee is to investigate the matter thoroughly, taking in to account all aspects of the issue including scientific, technical, legal etc, and submit its findings with clear and candid recommendations within a period of two months positively for the consideration / decision of DRAP and the Policy Board.

Decision:-

The Board noted and ratified the decision of reconstitution of the Committee.

Item No: VI. Registration of biological drugs.

Director (DBER) briefed the Board about ICH guidelines, SRA and WHO prequalification procedures for vaccines, as follows:

Vaccines originating from countries having Stringent Regulatory Authorities (SRA).

Background of ICH and SRA (http://ich.org):

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is unique in bringing together the regulatory authorities and pharmaceutical industry of Europe, Japan and the US to discuss scientific and technical aspects of drug registration. Since its inception in 1990, ICH has evolved, through its ICH Global Cooperation Group, to respond to the increasingly global face of drug development, so that the benefits of international harmonisation for better global health can be realised worldwide. ICH's mission is to achieve greater harmonisation to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner. In addition to the Drug Regulatory Authorities (DRAs) of Europe, Japan and the US, many other DRAs worldwide have chosen to implement some or all of the ICH Guidelines in their regulations.

Vaccines that are W.H.O. Prequalified for supply to United Nation agencies:

Background of WHO prequalification:

World Health Organization (WHO), through its Department of Immunization, Vaccines and Biologicals, provides advice to the United Nations Children's Fund (UNICEF) and other United Nations agencies on the acceptability, in principle, of vaccines considered for purchase by such agencies. This service is called prequalification. The purpose of the United Nations prequalification assessment is to provide assurance that candidate vaccines: (a) meet WHO recommendations on quality, safety and efficacy, including compliance with WHO's recommended standards for good manufacturing practices (GMP) and good clinical practice (GCP); and (b) meet the operational packaging and presentation specifications of the relevant United Nations agency. The aim is to ensure that vaccines provided through the United Nations

for use in national immunization services in different countries are safe, effective and suitable for the target populations at the recommended immunization schedules and with appropriate concomitant products. As vaccines purchased by United Nations agencies are required to meet WHO recommendations or guidelines (whichever are available), novel vaccines for which such recommendations are not available cannot be evaluated. In cases where a vaccine is made available for a disease of public health importance, the development of such guidelines will be prioritized by WHO and, as soon as a draft document becomes available, this can be used for evaluation for prequalification purposes. The fact that certain vaccines are not included on the list of prequalified vaccines does not mean that, if evaluated, they would be found not to comply with the required standards. WHO will define, in consultation with United Nations purchasing agencies, which vaccines are priorities for prequalification, and will make this information publicly available. Information on priority-setting for WHO vaccine prequalification is available on WHO website (WHO TRS 978, 2013).

Pakistan status of WHO prequalified vaccines:

In Pakistan the WHO prequalified vaccines are mostly used in EPI or other government institutions where bulk purchase is done through open tender or direct procurement through UNICEF. This WHO prequalification is some times used as an edge by the vendors to discredit other vaccines in the market whether locally manufactured or imported. As explained in WHO TRS 978, 2013 **"**The fact that certain vaccines are not included on the list of prequalified vaccines does not mean that, if evaluated, they would be found not to comply with the required standards" should be considered for each individual case in relation to the WHO compliance of the national regulatory authority for biological of each country.

Registration Board considered following products based on recommendations of ECBD and decided as recorded in last column of relevant table. All approved products are subject to compliance of import policy for finished drugs, storage verification (if not already done during last 02 years), MRP fixation by Drug Pricing Committee and other codal formalities. The Board also recommended DPC to fix MRP of these drugs keeping in view MRPs of other therapeutic equivalents, as demanded MRPs seem exorbitant.

Case No: 01. Biologicals originating from countries having stringent regulatory authorities.

S. No.	Applicant	Brand name and composition	Demanded MRP	4th ECBD Recommendation	Decision of Registration Board
1.	**Johnson & Johnson** Pakistan (Pvt) Ltd., Karachi. / M/s. Manufacturing, Labeling, Packaging & Release Site:- M/s. Cilag AG, Hochstrasse, Schaffhausen, Switzerland. Product License Holder**:-** M/s. Janssen-Cilag AG, Sihlbruggstrasse, Baar, Switzerland.	**Eprex ® 40,000 I.U** Pre-filled Syringe Each pre-filled syringes contains:- Erythropoietin alfa (Ph.Eur)……40,000 I.U (Erythropoietic Stimulating agent).	Rs.13,000/Per pre-filled syringe	Recommended, other strengths are already in use in Pakistan. Other strengths are: 2000IU (R.N. 013433) 4000IU (R.N. 011494) 10,000IU (R.N.014050) Application dated: 24.08.2011	Approved.
2.	Merck Specialties (Private) Limited, Karachi. M/s. Merck Serono S.P.A. VIA Delle Magnolie (LOC. Frazione Zona Industriale), Italy.	**Gonal-*f* Pen 300 IU (22 ug)/0.5ml Solution for Injection** in a pre-filled pen Each 0.5ml contains:- One cartridge delivers 300IU Follitropin Alpha, equivalent to 22 Micrograms. (Gonadotropins).	Rs.14,000/ Per 0.5ml	Recommended Application dated: 29.8.2011	Approved.
3.	Merck Specialties (Private) Limited, Karachi. M/s. Merck Serono S.P.A. VIA Delle Magnolie (LOC. Frazione Zona Industriale), Italy.	**Gonal-*f* Pen 450 IU (33 ug)/0.75ml Solution for Injection** in a pre-filled pen Each 0.75ml contains:- One cartridge delivers 450IU Follitropin Alpha, equivalent to 33 Micrograms. (Gonadotropins).	Rs.18,530/ Per 0.75ml	Recommended Application dated: 29.8.2011	Approved.

4.	Merck Specialties (Private) Limited, Karachi. M/s. Merck Serono S.P.A. VIA Delle Magnolie (LOC. Frazione Zona Industriale), Italy.	**Gonal-*f* Pen 900 IU (66 ug)/1.5ml Solution for Injection** in a pre-filled pen Each 1.5ml contains:- One cartridge delivers 900IU Follitropin Alpha, equivalent to 66 Micrograms. (Gonadotropins).	Rs.32,120/ Per 1.5ml	Recommended Application dated 29.8.2011	Approved.
5.	Merck Specialties (Private) Limited, Karachi. M/s. Merck Serono S.P.A. VIA Delle Magnolie (LOC. Frazione Zona Industriale), Italy.	**Ovidrel 250ug/0.5ml** Solution for Injection Pre-filled Syringe Each pre-filled syringe contains;- Choriogonadotropin alpha……250ug (Gonadotropins).	Rs.4800/Per Pre-filled Syringe	Recommended Application dated: 17.9.2011	Approved.
6.	Merck Specialties (Private) Limited, Karachi. M/s.Fleet Laboratories Limited, Richmansworth Road, Watford, United Kingdom.	**Crinone ® 8% Vaginal Gel** Each applicator contains:- 1.45g of Gel but delivers A controlled 1.125g of Gel (90mg Progesterone/1.125 G dose). (Progestin (Sex Hormones).	Rs.6880/Per 15 Single Pre-filled Applicator. Rs.458.66/Per Unit Pre-filled Applicator.	Recommended Application dated: 25.11.2011	Approved.
7.	**Popular International (Pvt)** Ltd., Karachi. M/s. Kedrion S.p.A Loc. Ai Conti, Castelvecchio Pascoli-Barga (LU), Italy.	**Uman Albumin Solution** for Infusion 250g/1-50ml vial Each 50ml vial contains:- Human Plasma Proteins containing at least 95% Albumin…….12.5g (Plasma Protein Solutions (Human).	Rs.5,775/ Per vial 50ml	Recommended based upon the approval process adopted by the respective SRA of the country of origin. Application date: 20.08.2011	Deferred for clarification of confirmation of similar formulation in Pakistan.

8.	Popular International (Pvt) Ltd., Karachi. M/s. Kedrion S.p.A Loc. Ai Conti, Castelvecchio Pascoli-Barga (LU), Italy.	**Uman Albumin Solution** for Infusion 200g/1-100ml vial Each 100ml vial contains:- Human Plasma Proteins containing at least 95% Albumin…….20g (Plasma Protein Solutions (Human).	Rs.9,450/ Per vial 100ml	Recommended based upon the approval process adopted by the respective SRA of the country of origin. Application date: 20.08.2011	Deferred for clarification of confirmation of similar formulation in Pakistan.
9.	**The Eastern Trade &** Distribution Co. (Pvt) Ltd., Karachi. M/s. Biotest Pharma GmbH, Landsteinerstrass Dreieich, Germany.	**Intratect ® Solution for Infusion** Each 1ml solution for infusion contains:- Human plasma proteins……50mg Thereof immunoglobulin G ≥ 96% (Human Immunoglobulin).	Rs.16,955/ 20ml Rs.35,323/ 50ml Rs.69,939/ 100ml Rs.138,480/ 200ml	Recommended based upon the approval process adopted by the respective SRA of the country of origin. Application date: 28.12.2010	Deferred for clarification of confirmation of similar formulation in Pakistan.
10.	**Wyeth Pakistan Limited**, Karachi. M/s. Pfizer Canada Inc. Saint-Laurent, Quebec, Canada.	**Premarin Vaginal Cream** Each gram of the cream contains:- Conjugated Estrogens……0.625 mg (Replacement hormone, Antineoplastic, Antiosteoporotic).	Rs.1535/Per pack of 14g tube	Recommended based upon the approval process adopted by the respective SRA of the country of origin. Date of application: 30.07.2012	Deferred for clarification for de-registration of previously registered Premarin Vaginal Cream.
11.	**GlaxoSmithKline, Karachi** Manufacturer: M/s Amgen Manufacturing Limited, Juncos, Puerto Rico, USA	**PROLIA** Solution for Injection (Denosumab 60mg) Each prefilled syringe contains 60mg of denosumab in 1ml solution (60mg/1ml) **Main indications:** Treatment of Osteoporosis & bone loss in patients undergoing hormone ablation for prostate or breast cancer	Each prefilled syringe containing 60mg/1ml Rs. 31,790/ pack of 1's	Recommended Date of Application: 21.11.2011	Approved.

12.	GlaxoSmithKline, Karachi Manufacturer: M/s Amgen Manufacturing Limited, Juncos, Puerto Rico, USA	**XGEVA** Solution for Injection (Denosumab 120mg) Each vial contains 120mg of denosumab in 1.7 ml solution (70mg/1ml) **Main indications:** For prevention of skeletal related events in patients with bone metastases from solid tumors.	Each vial containing 120mg / 1.7ml soln. Rs.63,130/ Pack of 1's	Recommended Date of Application 21.05.2012	Approved.
13.	GlaxoSmithKline, Karachi Marketting Authorization holder: Glaxo group Ltd, UK. Manufacturer site M/s Hospira Inc, Kansas, USA; Secondary packaging & Release site GlaxoSmithKline Manufacturing S.p.a., Pharma, Italy.	**BENLYSTA** Powder for infusion (Belimumab 120mg) Each vial contains 120 mg belimumab (80mg/ml after reconstitution) Diluent sterile water for injection to be registered separately and supplied free of cost **Main indications:** As add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematous (SLE) with a high degree of disease activity.	Each vial containing 120mg powder Rs. 12,397/ vial	Recommended Date of Application 07.06.2012	Approved. Registration Board also approved water for injection from same manufacturing site, as firm has submitted registration dossier and requisite fee. Expiry dates of both Benlysta and diluent shall be same.

14.	GlaxoSmithKline, Karachi Marketting Authorization holder: Glaxo group Ltd, UK. Manufacturer site M/s Hospira Inc, Kansas, USA; Secondary packaging & Release site GlaxoSmithKline Manufacturing S.p.a., Pharma, Italy.	**BENLYSTA Injection** (Belimumab 400mg) Each vial contains 400 mg belimumab (80mg/ml after reconstitution) Diluent sterile water for injection to be registered separately and supplied free of cost. **Main indications:** As add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematous (SLE) with a high degree of disease activity.	Each vial containing 400mg powder Rs. 41,324/ vial	Recommended Date of Application 07.06.2012	Approved. Registration Board also approved water for injection from same manufacturing site, as firm has submitted registration dossier and requisite fee. Expiry dates of both Benlysta and diluent shall be same.
15.	**Bayer Pakistan (Pvt)** Ltd., Karachi Manufacturer M/s Bayer Weimer GmbH und Co. KG Doebereinerstrasse 20 99427 Weimer, Germany.	**Qlaira** (eastradiol valerate/ Dienogest) Hormone combination Film coated tablets contains: 2/3mg estradiol valerate/Dienogest as active ingredients **Main indications:** Oral contraceptive; treatment of heavy menstrual bleeding in women without organic pathology who desire oral contraceptive	Pack of 1x28's tablets Rs 1900/-	Recommended based upon the approval process adopted by the respective SRA of the country of origin. Date of Application received 29.08.2011	Approved

16.	Bayer Pakistan (Pvt) Ltd., Karachi Manufacturer M/s Bayer Pharma AG Müllerstraße 178 13353 Berlin, Germany.	**Eylea** Solution for injection (Aflibercept) 40mg/ml Each vial contains Aflibercept 40 mg/ml (recombinant homodimeric glycoprotein, MW 115,000 D aproximately) **Main indications:** New vascular (wet) age related macular denegeration (wet AMD); Macular edema following central vien occlusion (CRVO).	Vial 1's Rs.120,000/	Recommended based upon the approval process adopted by the respective SRA of the country of origin. Date application received: 29.03.2013	Approved
17.	**Pfizer Pakistan Limited, Karachi** **Manufacturer:** Pfizer Manufacturing Belgium NV, Rijksweg 12, 2870 Puurs, Belgium.	**Sayana Press** 104mg/0.65ml (Medroxyprogesterone acetate) Pre-filled injection system contains Depo-medroxyprogesterone acetate (DMPA) 104mg/0.65ml **Main indications:** Contraceptive, depot effective for at least 13 weeks.	For initial at least two years the product will be supplied free of cost to females belonging to poor and low income group, Costing data will be provided to DPC.	Recommended based upon the approval process adopted by the respective SRA of the country of origin. Date application received: 08.01.2013	Approved. However, comments of Directorate of Cost & Pricing will be taken on firm's submission about MRP.

Case No:02. Vaccines from countries having SRA.

18.	**GlaxoSmith Kline** Pakistan Ltd., Karachi. / Manufacturer: M/s.GlaxoSmithKline Biologicals, Rixensart Belgium.	**Boostrix** Vaccine, each 1 dose (0.5ml) contains:- Diphtheria Toxoid not less than 2 IU Tetanus Toxoid not less than 20 IU *Bordetella pertussis* antigens: Pertussis Toxoid: 8mcg Filamentous Haemagglutinin: 8mcg Pertactin: 2.5mcg **Main Indications:** Booster vaccination against diphtheria, tetanus and pertussis in individuals from age four years onwards.	Pre-filled syringe Pack of 1's Rs. 4000/	Recommended Date application received: 17.10.2011	Approved
19.	GlaxoSmithKline Pakistan Limited, Karachi. / Manufacturer: M/s. GlaxoSmithKline Biologicals, S.A. Belgium.	**Twinrix adult** Suspension for injection. Each pre-filled syringe contains:- Inactivated Hepatitis A virus…720 ELISA Units Hepatitis B surface antigen (rDNA).....20 micrograms (Combined viral vaccine for protection against Hepatitis A and B).	Pre-filled syringe Pack of 1's Rs. 4000/	Recommended Date application received: 03.11.2010	Deferred for expert opinion of Gen (R) Karamat Gen (R) Tasawar Brig (R) Najmi Prof Umar

20.	**Hospital Services &** Sales, Karachi. Manufacturer: M/s. Serum Institute of India Ltd., Pune, Maharashtra State, India.	**Nasovac** (Influenza Vaccine), Human Live Attenuated Freeze Dried Pandemic H1N1 Vaccine) Each 0.5ml single dose contains:- 1 dose of 0.5ml containing not less than $10^{7.0}$ EID_{50} of the live attenuated Influenza virus reassortant of the pandemic (H1N1) 2009 virus: A/California/7/2009/ 38 (H1N1) like strain. (Vaccine).	Rs.1000/ Per 01 vial x 0.5ml (05 doses) Full fee not deposited	Recommended	Deferred, as revised fee not deposited
21.	**Macter International** Limited, Karachi. Manufacturer: M/s. Green Signal Biopharma Private Limited, Tamil Nadu, India.	**BCG ONCO BP** Freeze Dried Vaccine Each vial contains:- 40mg Bacillus Calmette Guerin-Colony Forming Units 1 to 8 x 10^8 **Main Indication:** Immunotherapy in urinary bladder cancer	Price not mentioned.	Recommended Date of Application: 29.05.2012	Approved
22.	**Sanofi Aventis Pakistan** Limited, Karachi. M/s. Sanofi Pasteur, SA, Lyon, France.	**Verorab** Suspension for injection Each dose of reconstituted vaccine (0.5ml) contains:- Rabies virus,Wistar rabies PM/WI 38 1503-3M strain (inactivated)…….≥ 2.5 IU (Viral Vaccine)	Rs.3750/Per pack of 5 vials	Recommended Verorab in single dose pack is already registered, this case is of 1x5 vials pack	Registration Board approved additional pack of 5 vials subject to MRP fixation bu DPC.

23.	Sanofi Aventis Pakistan Limited, Karachi. M/s. Sanofi Pasteur, SA, Lyon, France.	**Vivaxim** Suspension and Solution for injection in a Prefilled dual-chamber syringe Each dose of reconstituted vaccine (1ml) contains:- Vi capsular polysaccharides of Salmonella typhi (Ty2 strain)…….25 micrograms) Hepatitis A virus, GBM strain inactivated 160 units (Bacterial and Viral Vaccine)	Rs.11,200 / Per 1ml-1 dose pre-filled dual chamber syringe	Recommended	Deferred for expert opinion of Gen (R) Karamat Gen (R) Tasawar Brig (R) Najmi Prof Umar
24.	Sanofi Aventis Pakistan Limited, Karachi. Shanta Biotech Limited. Survey No.274, Athvelli Village, Medchal, Mandal-501401, Rangareddy, District Andhra Pradesh, India.	**ShanTT** Suspension for Injection Each dose of 0.5ml contains:- Tetanus Toxoid…≥……40 IU (Vaccine)	Rs.70/Per 0.5ml single vial Rs.2450/Per pack of pack of 35 x 0.5ml single dose vial	Recommended	Approved

25.	Sanofi Aventis Pakistan Limited, Karachi. M/s Sanofi Pasteur, SA 2, Avenue du Pont Posteur, 69 007 Lyon. France.	**Imovax Polio** Suspension for Injection in multi dose Poliomyelitis vaccine (inactivated against type 1,2 & 3 Polio Virus) One dose 0.5ml contains:- Poliovirus Type1, Mahoney strain (inactivated)…… 40 DU Poliovirus Type2, MEF-1 strain (inactivated)…… 8 DU Poliovirus Type3, Saukett strain (inactivated)…… 32 DU	1 vial of 5ml (10 doses of 0.5ml) =Rs.4240/- 10 vial of 5ml (100 doses of 0.5ml) =Rs.4400/-	Recommended, Each packing will be registered separately	Approved This product will be registered for use in EPI and institution only

26.	Sanofi Aventis Pakistan Limited, Karachi/ Manufacturing Facility:- Shanta Biotech Limited. Survey No.274, Athvelli Village, Medchal, Mandal-501401, Rangareddy, District Andhra Pradesh, India.	Shan TT ® (Adsorbed Tetanus Vaccine) Each dose of 0.5ml contains:- Tetanus Toxoid…≥ 40IU Almonium Phosphate Gel…….0.425mg Thiomersal…..0.025mg	Rs.70/-per 0.5ml single does. Rs.1400/- per 10ml-20 doses vial. Rs.42000/- per pack of 30 x 10ml multi dose vial.	Recommended	Approved

27.	Sanofi Aventis Pakistan Limited, Karachi/ Manufactured by:- M/s Sanofi Pasteur, SA 2, Avenue du Pont Pasteur 69 007 lyon, France.	**Hexaxim Suspension for Injection** (Diphtheria, Tetanus, Pertussis (Acellular component), Hepatitis-B (rDNA), Poliomyelites (Inactivated) and Heamophilus Influenzae Type-B Conjugate Vaccine (Adsorbed). Each dose of fully liquid vaccine (0.5ml) contains:- Purified diphtheria toxoid…….≥ 20 IU. Purified tetanus toxoid……..≥ 40 IU. Bordetella pertussis antigen: Pertussis toxoid…..25 mcg Filamentous Haemagglutinin….25 mcg Inactivated Poliomyelitis virus:- Type 1 (Mahoney)……..D antigen: 40 units Type 2(MEF-1) ……D antigen: 8 units. Type 3 (Sauket) ……D antigen: 32 units Hepatitis B Surface antigen……. 10mcg Haemophilus Influenzae type-B Polysaccharide (Polyrivosylrivitol phosphate) conjugated to tetanus protein (tetanus protein: 22-36 mcg)……12mcg (Express as amount of polysaccharide.	Rs.3300/- per 0.5ml Pre-filled syringe.	Recommended	Approved

28.	Sanofi Aventis Pakistan Limited, Karachi/ Product License Owner: Sanofi Pasteur Limited 87/2 CRC Tower 23rd Floor, All seasons place, wireless road, Lumpini, Pathumwan Bangkok, Thailand. Manufactured by:- M/s GPO-MBP (Government Pharmaceutical Organization-Merieux Biological Product) Co. Ltd, 241 moo7, Gateway City Industrial Estate, Huasamrong, Plaengyao, Chachoengsao, Thailand.	**Imojev Japanese Encephalitis Vaccine** (Live, Inactivated) Powder and Solvent for Suspension for Injection. Each dose of reconstituted vaccine (0.5ml; 1dose) contains:- Lyophilisate Live, attenuated, recombinant Japanese encephalitis virus…….. …4.0-5.8 $\log_{10}$ PFU Diluent (0.5ml) 0.4% sterile NaCl Solution, will be registered separately	Single dose of vaccine 0.5ml =Rs.5040/-	Recommended	Approved Registration Board also approved water for injection from same manufacturing site, as firm has submitted registration dossier and requisite fee. Expiry dates of both Imojev Japanese Encephalitis Vaccine and diluent shall be same.

29.	Sanofi Aventis Pakistan Limited, Karachi/ Product License Owner: Sanofi Pasteur Limited 87/2 CRC Tower 23rd Floor, All seasons place, wireless road, Lumpini, Pathumwan Bangkok, Thailand. Manufactured by:- M/s GPO-MBP (Government Pharmaceutical Organization-Merieux Biological Product) Co. Ltd, 241 moo7, Gateway City Industrial Estate, Huasamrong, Plaengyao, Chachoengsao, Thailand.	**Imojev MD, Japanese Encephalitis Vaccine** (Live, Inactivated) Powder and Solvent for Suspension for Injection. Each dose of reconstituted vaccine (0.5ml; 1dose) contains:- Lyophilisate Live, attenuated, recombinant Japanese encephalitis virus…….. …4.0-5.8 $\log_{10}$ PFU Diluent (0.5ml) 0.9% sterile NaCl Solution will be registered separately	1 dose (0.5ml) =Rs5040 4 dose vial= Rs20,160 10 vial x 4 doses (40 doses)= Rs.201,600/-	Recommended Each packing will be registered separately	Approved Registration Board also approved water for injection from same manufacturing site, as firm has submitted registration dossier and requisite fee. Expiry dates of both Imojev MD Japanese Encephalitis Vaccine and diluent shall be same.
30.	Sanofi-aventis Pakistan Limited, Karachi. / Shanta Biotech Limited. Survey No.274, Athvelli Village, Medchal, Mandal-501401, Rangareddy, District Andhra Pradesh, India.	**Shanvac-B 0.5ml Injection** Each 0.5ml Pediatric dose contains:- r-DNA Hepatitis –B surface antigen purified……10mcg (Vaccine).	Rs.280/Per single dose vial of 0.5ml	Recommended	Approved

31.	Sanofi Aventis Pakistan Limited, Karachi/ Administrative Headquarter: Shantha (A Sanofi Compnay), Vasantha Chambers Fateh Maidan Road,Basheer Bagh Hyderabad AP India. Manufacturing Facility:- Survey No.274, Athvelli Village Medchal Mandal-501401 Rangareddy District, Andhra Pradesh, India.	**Shanvac-B** (rDNA Hepatitis-B Surface Antigen purified. (10 paediatric doses) Paediatric dose of 0.5ml contains:- rDNA Hepatitis-B Surface Antigen purified…..10mcg AlOH gel eq to Al+++……..0.25mg Thiomersal...0.025mg	10 vials x 5ml (100doses) = Rs.28,000/-	Recommended	Approved Registration is exclusively for supply to EPI and institutions only.

32.	Sanofi Aventis Pakistan Limited, Karachi/ Manufactured by: Administrative Headquarter: Shantha (A Sanofi Compnay), Vasantha Chambers Fateh Maidan Road,Basheer Bagh Hyderabad AP India. Manufacturing Facility:- Survey No.274, Athvelli Village Medchal Mandal-501401 Rangareddy District, Andhra Pradesh, India. **VACCINE**	**ShanTT** (Adsorbed Tetanus Vaccine) Each single dose of 0.5ml in multi dose vial contains:- Tetanus Toxoid …….. ……≥ 40 IU. Aluminum Phosphate gel eq to Al+++…...0.425mg Thiomersal…….0.05 mg	30 vials x 5ml = Rs.21,000/- multi dose vial.	Recommended	Approved Registration is exclusively for supply to EPI and institutions only.
33.	**Shah Enterprises**, 41-44, Akbar Market, Jang Building, Muree Road, Rawalpindi cantt. Naked vial import from: M/s Green Signal Pvt Ltd., India. And local labeling	**BCG Vaccine** (Freeze – Dried BP) Each Vial contains 1mg of Bacillus Calmette Guerin (BCG) freeze-Dried. (Unit/Dose 1mg) (1.5%w/v) (Vaccine)		Recommended	Deferred for clarification on local labeling, quality control and release site. The Board also advised to prepare working paper regarding import of naked vials in light of prevailing rules.

34.	**Sind Medical Stores,** Karachi. M/s. Institute Pasteur Dakar, Senegal.	**Yellow Fever Vaccine** Each 0.5ml dose of rehydrated vaccine contains:- Lyophilized suspension of live yellow fever vaccine, 17 D strain, cultivated in live SPF chick embryos: 1000 LD 50 minimum (WHO standards) (Vaccine). Diluent to be supplied free of cost with vaccine and is to regsitered	Rs.19264/ Per vial of 10 doses Rs.1926/Per dose	Recommended	Approved. Registration Board also approved water for injection from same manufacturing site, as firm has submitted registration dossier and requisite fee. Expiry dates of both Yellow Fever Vaccine and diluent shall be same.
35.	**Hospital Services & Sales, Karachi.** Imported from Federal State Unitary Enterprise on Manufacture of Bacterial and Viral Preparations of Chumakov Institute of Poliomyelitis & Viral Encephalitis, Russian Academy of Medical Sciences, Russia.	**Yellow fever vaccine** (live Freezedried) Each single 0.5ml dose of vaccine contains: Yellow fever virus no less than 1,000 LD_{50} or 1,600 PFU Supplied with diluent water for injection 1.25 ml and 3 ml in ampoules and are to be registered	2 doses ampoules / 1.0 ml and 5 doses ampoules / 2.5 ml		Approved. Separate registration numbers will be allotted for both volumes. Registration Board also approved water for injection from same manufacturing site, as firm has submitted registration dossier and requisite fee. Expiry dates of both Yellow Fever Vaccine and diluent shall be same.

36.	Sind Medical Stores, Karachi. Bilthoven Biologicals B.V., Al Bilthoven, The Netherlands.	**Poliomyelitis Vaccine** Inactivated, Suspension for injection-0.5ml vial/1 dose One dose of 0.5ml Inactivated Poliomyelitis vaccine contains the following active ingredients: i. Poliomyelitis virus type 1 (Mahoney) 40D-antigen units ii. Poliomyelitis virus type 2 (MEF 1) 8 D-antigen units iii. Poliomyelitis virus type 3 (Saukett) 32-D antigen units	Rs. 961/ 0.5 ml/dose /vial	Recommended	Approved
37.	Sind Medical Stores, Karachi. M/s. Serum Institute of India Ltd., Hadapsar, Pune, India.	**Diphtheria & Tetanus Vaccine Adsorbed** for Adults and Adolescents 1 dose/0.5ml Vial Each single dose of 0.5ml contains:- Diphtheria Toxoid…≤5 Lf (≥2 IU) Tetanus Toxoid….≥5 Lf (≥40 IU) Adsorbed on Aluminum Phosphate, AI+++……≤1.25mg Preservative:Thiomersal…..0.01% (Vaccine)	Rs.530/Per 1 dose/0.5ml Vial	Recommended	Approved

38.	Sind Medical Stores, Karachi. M/s. Serum Institute of India Ltd., Hadapsar, Pune, India.	**Diphtheria & Tetanus Vaccine Adsorbed** for Adults and Adolescents 10 dose / 05ml Vial Each single dose of 0.5ml contains:- Diphtheria Toxoid…≤5 Lf (≥2 IU) Tetanus Toxoid…≥5 Lf (≥40 IU) Adsorbed on Aluminum Phosphate, AI+++……≤1.25mg Preservative:Thiomersal….0.01% (Vaccine)	Rs.2050/Per 10 dose/5ml Vial	Recommended	Approved This product will be registered for use in EPI and institution only
39.	Sind Medical Stores, Karachi. M/s. Serum Institute of India Ltd., Hadapsar, Pune, India. **WHO PREQUALIFIED VACCINE**	**Diphtheria & Tatanus Vaccine Adsorbed** for Adults and Adolescents 20 dose / 10ml Vial Each single dose of 0.5ml contains:- Diphtheria Toxoid…….≤5 Lf (≥2 IU) Tetanus Toxoid…≥5 Lf (≥40 IU) Adsorbed on Aluminum Phosphate, AI+++……≤1.25mg Preservative:Thiomersal…..0.01% (Vaccine)	Rs.3308/Per 20 dose/10 Vial	Recommended	Approved This product will be registered for use in EPI and institution only
40.	Sind Medical Store, Karachi. M/s Changchun BCHT Biotechnology Co., China	**Sterile water for injection 0.5mL** forVaxapx, live attenuated varicella vaccine is already registered vide reg no. 074628	Free with vaccine	Recommended Full Rs100,000/ fee paid	Approved. Diluent and drug will have same expiry dates.

41.	Sind Medical Store, Karachi. M/S Bharat Biotech International Limited, India	**Diluent for Inidrab** injection-1.0 mL Indirab is approved and 0.5 ml is registered vide reg no. 053814	Free with vaccine	Recommended Full Rs100,000/ fee paid	Approved. Approved. Diluent and drug will have same expiry dates.
42.	M/s Hospital Services and Sales, Karachi M/s Serum Institute of India Ltd., India	**Diluent for BCG vaccine** Sodium Chloride Injection BP-1 ml ampoule for reconstitution of BCG vaccine reg no. 053816	Free with vaccine	Recommended Full Rs100,000/ fee paid	Approved. Approved. Diluent and drug will have same expiry dates.
43.	**Amson Vaccine & Pharma** (Pvt) Ltd., Islamabad. Import from M/s Biological E Ltd., Shameerpet Mandal, Andhra Pradesh, India	**DTwP-rHepB-Hib** vaccine Each 1 ml contains: Diphtheria Toxoid 25Lf(≥30IU) Tetanus Toxoid 5.5Lf(≥60IU) B. pertussis (Whole cell) 16IOU(≥4IU) r-HBsAg 12.5 mcg Purified capsular polysaccharide 11 mcg Tetanus Toxoid (Carrier protein) 20 to 36.7mcg Al^{+++} (as $AlPO_4$) ≤1.25 mg Thiomersal BP 0.01%w/v	1 dose vial containing 0.5ml, and 10 dose vial containing 5 ml Rs 3000/dose	Recommended Each packing will be registered separately	Approved This product will be registered for use in EPI and institution only

Case No;03. Human Biologicals for local manufacture

Registration Board discussed matter regarding manufacturing of biological drugs locally and decided to inspect all these facilities for confirmation of product specification, manufacturing and quality control facilities for applied products by following panel.

- Dr Khalid Khan, Director DTL Peshawar
- Dr Ammanullah Khan, Director DTL Queta
- Area FID Karachi

- Director, NCLB, Islamabad

Registration Board also constituted a committee comprising of its following members for evaluation of these inspection reports. This committee will frame its recommendations keeping in view inspection reports and evaluation of ECBD for consideration of Registration Board.

- Gen (R) Karamat A Karamat
- Brig (R) Muzammil H Najmi
- Dr. Muhammad Arshad
- Mr. A.Q. Javid Iqbal
- Director, DBER.

44.	**Getz Pharma, Karachi** API (Drug substance) (in powder form) will be imported from M/s Hybio Pharmaceutical Co. Ltd, No.37, Keji C. Str. 2nd, Shenzhen Hi-Tech Industrial Park for local formulation.	**Eptifib** Solution for Infusion 75mg/100ml Each ml contains: Eptifibatide….0.75 mg (Anti-thrombotic agent) **(Local manufacture)**	100ml Rs.9,900/- per vial	Recommended subject to the clarifications on specifications of the raw material analysis.
45.	Getz Pharma, Karachi API (in powder form) will be imported from M/s Hybio Pharmaceutical Co. Ltd, No.37, Keji C. Str. 2nd, Shenzhen Hi-Tech Industrial Park for local formulation.	**Eptifib** Solution for Injection 2mg/ml Each ml contains: Eptifibatide….2mg (Anti-thrombotic agent) **(Local manufacture)**	10ml Rs.3150/-	Recommended subject to the clarifications on specifications of the raw material analysis.

46.	Getz Pharma, Karachi API (in powder form) will be imported from M/s Hebei Changshan Biochemical Paharmaceutrical Co., Ltd., Shijiazhuang China for local formulation. Biosimilar of Clexane of Sanofi	**Enoxa Injection** 20mg/0.2ml Injection Each **Pre-filled syringe** contains:- Enoxaparin sodium…..20 mg USP (Antithrombotic agent) **(Local manufacture)**	0.2mlx 2's Rs.355/- Pre-filled syringes.	Recommended Subject to establishment of stability and bioequivalence study with the innovator product in the country of origin
47.	Getz Pharma, Karachi API (in powder form) will be imported from M/s Hebei Changshan Biochemical Paharmaceutrical Co., Ltd., Shijiazhuang China for local formulation. Biosimilar of Clexane of Sanofi.	**Enoxa** 40mg/0.4ml Injection Each **Pre-filled syringe** contains:- Enoxaparin sodium…..40 mg USP (Antithrombotic agent) **(Local manufacture)**	0.4mlx 2's Rs.625/- Pre-filled syringes.	Recommended Subject to establishment of stability and bioequivalence study with the innovator product in the country of origin

48.	Getz Pharma, Karachi API (in powder form) will be imported from M/s Hebei Changshan Biochemical Paharmaceutrical Co., Ltd., Shijiazhuang China for local formulation. Biosimilar of Clexane of Sanofi.	**Enoxa** 60mg/0.6ml Injection Each **Pre-filled syringe** contains:- Enoxaparin sodium…..60 mg USP (Antithrombotic agent) **(Local manufacture)**	0.6mlx 2's Rs.801/- Pre-filled syringes.	Recommended Subject to establishment of stability and bioequivalence study with the innovator product in the country of origin
49.	Getz Pharma, Karachi API (in powder form) will be imported from M/s Hebei Changshan Biochemical Paharmaceutrical Co., Ltd., Shijiazhuang China for local formulation. Biosimilar of Clexane of Sanofi.	**Enoxa** 80mg/0.8ml Injection Each Pre-filled syringe contains:- Enoxaparin sodium....80mg (Antithrombotic agent) **(Local manufacture)**	0.8mlx2's Rs.973/- pre-filled syringes.	Recommended Subject to establishment of stability and bioequivalence study with the innovator product in the country of origin

50.	Getz Pharma, Karachi API to be imported from M/s Hybio Pharmaceutical Co. Ltd, No.37, Keji C. Str. 2nd, Shenzhen Hi-Tech Industrial Park for local formulation. Copaxone (Glatiramer acetate) solution for injection 20mg/ml from Teva Phamaceuticals Ltd USA.	**Gilia solution for injection** Glatiramer acetate 20mg/ml Each ml contains: Glatiramer acetate 20mg	1 PFS Rs 15,000 3PFS Rs45,000	Form d
51.	Getz Pharma, Karachi API (in powder form) will be imported from M/s Hybio Pharmaceutical Co. Ltd, No.37, Keji C. Str. 2nd, Shenzhen Hi-Tech Industrial Park for local formulation.	**Lira Solution for injection** 6mg/ml Solution for Injection in Cartridge Each 1ml contains:- Liraglutide (free-base anhydrous)…….. 6mg (Anti Diabetic) **(Local manufacture)**	1's Rs.20,000/- Per Cartridge. 1x3's Cartridge Rs.60,000/-	Form d

52.	**Getz Pharma, Karachi** Naked filled vials containing lyophilized powder for injection will be imported from M/s Shanghai Livzon Pharmaceutical Co. Ltd, No.1150, Guiqiao Road, Jinqiao Export Processing Zone, Pudong, Shanghai, China and will be repacked locally.	**Menocon** Lyophilized Powders for Injection 1000 IU USP Each vial contains:- Human Chorionic Gonadotropin USP….....1000 IU (Gonadotropins and ovulation stimulants) **(Local manufacture)**	1 vial Rs.500/- 1x5's Rs.2500 /- 1x10's Rs.5000 /-	Recommended
53.	**Getz Pharma, Karachi** Naked filled vials containing lyophilized powder for injection will be imported from M/s Shanghai Livzon Pharmaceutical Co. Ltd, No.1150, Guiqiao Road, Jinqiao Export Processing Zone, Pudong, Shanghai, China and will be repacked locally.	**Menocon** Lyophilized Powders for Injection 5000 IU USP Each vial contains:- Human Chorionic Gonadotropin USP….....5000 IU (Gonadotropins and ovulation stimulants) **(Local manufacture)**	1 vial Rs.1000 /- 1x5's Rs.5000 /- 1x10's Rs.1000 0/-	Recommended

54.	**Getz Pharma, Karachi** Naked filled vials containing lyophilized powder for injection will be imported from M/s Shanghai Livzon Pharmaceutical Co. Ltd, No.1150, Guiqiao Road, Jinqiao Export Processing Zone, Pudong, Shanghai, China and will be repacked locally. Menopur from Ferring Pharmaceuticals UK	**Menoget** Menotropins 75IU / vial Each vial contains: Menotropins USP 75IU (Human menopausal gonadotrophin) (Gonadotropins and Ovulation stimulants)	1 vial Rs. 1500, 1x5 vials Rs. 7,000 1x10 vials Rs, 15,000	Recommended
55.	**Getz Pharma, Karachi** Naked filled vials containing lyophilized powder for injection will be imported from M/s Shanghai Livzon Pharmaceutical Co. Ltd, No.1150, Guiqiao Road, Jinqiao Export Processing Zone, Pudong, Shanghai, China and will be repacked locally. Menopur from Ferring Pharmaceuticals UK	**Menoget** Menotropins 150IU / vial Each vial contains: Menotropins USP 150IU (Human menopausal gonadotrophin) (Gonadotropins and Ovulation stimulants)	1 vial Rs. 3000, 1x5 vials Rs. 15,000 1x10 vials Rs, 30,000	Recommended

56.	Getz Pharma, Karachi Pegylated filgrastim will be imported in liquid form from M/s Beijing Kawin Technology Share-Holding Co., Ltd, No.6 Rongjing East Street, BDA, Beijing, China for further formulation locally.	**Neupeg injection** 6mg/0.6ml Injection Each Pre-Filled syringe contains:- Pegfilgrastim……..6mg (GCSF) **(Local manufacture)**	0.6ml Rs.60,000/-	Recommended
57.	Getz Pharma, Karachi API (in concentrated solution form) will be imported from M/s Beijing Kawin Technology Share-Holding Co., Ltd, No.6 Rongjing East Street, BDA, Beijing, China for local formulation.	**Getiferon Solution for Injection** **3 MIU in Vials** Each vial contains:- Recombinant Human **Interferon Alfa 2a** …….$3x10^6$ IU EP Human Albumin ….....5mg Sodium Chloride ...….9mg Water for Injection .Q.S to 1ml (Anti Viral) **(Local manufacture)**	Rs.1200/- per vial Five vials Rs.6000/-	Recommended

58.	Getz Pharma, Karachi API (in concentrated solution form) will be imported from M/s Beijing Kawin Technology Share-Holding Co., Ltd, No.6 Rongjing East Street, BDA, Beijing, China for local formulation.	**Getiferon** Solution for Injection **5MIU** in **Vials** Each vial contains:- Recombinant Human **Interferon Alfa 2a** …5x10^6 IU EP Human Albumin ……5mg Sodium Chloride ...…9mg Water for Injection .Q.S to 1ml (Anti Viral) **(Local manufacture)**	1's Rs.1500 /- Per vial 1x5 vials Rs.7500 /-	Recommended
59.	Getz Pharma, Karachi API (in concentrated solution form) will be imported from M/s Beijing Kawin Technology Share-Holding Co., Ltd, No.6 Rongjing East Street, BDA, Beijing, China for local formulation.	**Getiferon Solution for Injection 3 MIU** in **Pre-Filled Syringes** Each Pre-Filled Syringe contains:- Recombinant Human **Interferon Alfa 2a** …….3x10^6 IU EP Human Albumin …….5mg Sodium Chloride ……9mg Water for Injection .Q.S to 1ml (Anti Viral) **(Local manufacture)**	1's Rs.1200 /- per pre-filled syringe. 5's pre-filled syringes Rs.6000 /-	Recommended

60.	Getz Pharma, Karachi API (in concentrated solution form) will be imported from M/s Beijing Kawin Technology Share-Holding Co., Ltd, No.6 Rongjing East Street, BDA, Beijing, China for local formulation.	**Getiferon Solution for Injection** **5 MIU** in **Pre-Filled Syringes** Each Pre-Filled Syringe contains:- Recombinant Human **Interferon Alfa 2a** …….$5x10^6$ IU EP Human Albumin …….5mg Sodium Chloride ……9mg Water for Injection .Q.S to 1ml (Anti Viral) **(Local manufacture)**	1's Rs.1500 /- per pre-filled syringe. 5's pre-filled syringes Rs.7500 /-	Recommended
61.	Getz Pharma, Karachi API (in concentrated solution form) will be imported from M/s Beijing Kawin Technology Share-Holding Co., Ltd, No.6 Rongjing East Street, BDA, Beijing, China for local formulation.	**Uniferon Solution for Injection** **3 MIU in Vials** Each vial contains:- Recombinant Human **Interferon Alfa 2b**…….$3x10^6$ IU EP Human Albumin …....5mg Sodium Chloride ...….9mg Water for Injection .Q.S to 1ml (Anti Viral)	1's Rs.1200 /- per pre-filled syringe. 5's pre-filled syringes Rs.6000	Recommended

62.	Getz Pharma, Karachi API (in concentrated solution form) will be imported from M/s Beijing Kawin Technology Share-Holding Co., Ltd, No.6 Rongjing East Street, BDA, Beijing, China for local formulation.	**Uniferon Solution for Injection** **5 MIU in Vials** Each vial contains:- Recombinant Human **Interferon Alfa 2b**…….$5x10^6$ IU EP Human Albumin …....5mg Sodium Chloride ...….9mg Water for Injection .Q.S to 1ml (Anti Viral)	1's Rs.1500 /- per pre-filled syringe. 5's pre-filled syringes Rs.7500	Recommended
63.	Getz Pharma, Karachi API (in concentrated solution form) will be imported from M/s Beijing Kawin Technology Share-Holding Co., Ltd, No.6 Rongjing East Street, BDA, Beijing, China for local formulation.	**Uniferon Solution for Injection** **3MIU** in **Pre-Filled Syringe** Each Pre-Filled Syringe contains:- Recombinant Human Interferon Alfa 2b ……..$3x10^6$ IU Human Albumin ……5mg Sodium Chloride ……9mg Water for Injection .Q.S to 1ml (Anti Viral) **(Local manufacture)**	Rs.1500 /- Per pre-filled syringe.	Recommended

64.	Getz Pharma, Karachi API (in concentrated solution form) will be imported from M/s Beijing Kawin Technology Share-Holding Co., Ltd, No.6 Rongjing East Street, BDA, Beijing, China for local formulation.	**Uniferon** Solution for Injection **5MIU** in **Pre-Filled Syringes** Each Pre-Filled Syringe contains:- Recombinant Human **Interferon Alfa 2b** …….5x10^{6} IU Human Albumin …….5mg Sodium Chloride ……9mg Water for Injection .Q.S to 1ml (Anti Viral) **(Local manufacture)**	Rs.2100 /- Per pre-filled syringe.	Recommended
65.	**Macter International** Limited, Karachi (API Import in concentrated bulk from M/s Beijing Shuanglu Pharmaceutical Company Ltd, China and local formulation at M/s Macter International, F-216, SITE, Karachi)	**Heberon 2a Injection** 3MIU/0.3ml. (Liquid Solution) Each vial contains:- rh-Interferon alpha 2a ……...3MIU (Anti viral anti proliferative Immunomodulato r) **(Local manufacture)**	1's Rs.600/- per vial.	Recommended

66.	Macter International Limited, Karachi (API Import in concentrated bulk from M/s Beijing Shuanglu Pharmaceutical Company Ltd, China and local formulation at M/s Macter International, F-216, SITE, Karachi)	**Heberon 2a Injection** 5MIU/0.5ml. (Liquid Solution) Each vial contains:- rh-Interferon alpha 2a …….5MIU (Anti viral anti proliferative Immunomodulator) **(Local manufacture)**	1's Rs.1000 /-	Recommended
67.	Macter International Limited, Karachi F-216, SITE, Karachi (API Import in concentrated bulk from M/s Beijing Shuanglu Pharmaceutical Company Ltd, China and local formulation and freeze-drying at M/s Macter International, F-216, SITE, Karachi)	**Heberon 2a Injection** 3MIU/ml (Lyophilized Powder) Each vial contains:- rh-Interferon alpha 2a …….…3MIU (Anti viral anti proliferative Immunomodulator) **(Local manufacture)**	1ml Rs.1086 /- per vial.	Recommended

68.	Macter International Limited, Karachi , F-216, SITE, Karachi (API Import in concentrated bulk from M/s Beijing Shuanglu Pharmaceutical Company Ltd, China and local formulation and freeze-drying at M/s Macter International, F-216, SITE, Karachi)	**Heberon 2a Injection** 5MIU/ml (Lyophilized Powder) Each vial contains:- rh-Interferon alpha 2a ……5MIU (Anti viral anti proliferative Immunomodulator) **(Local manufacture)**	1ml Rs.1761/- per vial	Recommended
69.	Macter International Limited, Karachi , F-216, SITE, Karachi (API Import in concentrated bulk from M/s Intas Pharmaceuticals Ltd, India and local formulation and freeze-drying at M/s Macter International, F-216, SITE, Karachi)	**Peg-In Injection** 50mcg /0.5ml Each vial contains:- Pegylated rh-Interferon alfa 2b…….50mcg (Lyophilized powder for injection) Diluent to be supplied with each vial (Anti viral anti proliferative Immunomodulator) **(Local manufacture)**	0.5ml Rs.4,480/- per vial. Diluent to be supplied free of cost and requires separate regsitration	Recommended

70.	Macter International Limited, Karachi , F-216, SITE, Karachi (API Import in concentrated bulk from M/s Intas Pharmaceuticals Ltd, India and local formulation and freeze-drying at M/s Macter International, F-216, SITE, Karachi)	**Peg-In Injection** 80mcg /0.5ml Each vial contains:- Pegylated rh-Interferon Alfa 2b……..80mcg (Lyophilized powder for injection) (Anti viral anti proliferative Immunomodulator) Diluent to be supplied with each vial **(Local manufacture)**	0.5ml Rs.7153 /- per vial Diluent to be supplied free of cost and requires separate regsitration	Recommended
71.	Macter International Limited, Karachi , F-216, SITE, Karachi (API Import in concentrated bulk from M/s Intas Pharmaceuticals Ltd, India and local formulation and freeze-drying at M/s Macter International, F-216, SITE, Karachi)	**Peg-In Injection** 100mcg /0.5ml Each vial contains:- Pegylated rh-Interferon alfa 2b……..100mcg (Lyophilized powder for injection) (Anti viral anti proliferative Immunomodulator) Diluent to be supplied with each vial **(Local manufacture)**	0.5ml Rs.9,520 /- per vial Diluent to be supplied free of cost and requires separate regsitration	Recommended

72.	**Macter International** Limited, Karachi (API Import in concentrated bulk from M/s Intas Pharmaceuticals Ltd, India and local formulation and freeze-drying at M/s Macter International, F-216, SITE, Karachi)	**Peg-In Injection** 120mcg /0.5ml Each vial contains:- Pegylated rh-Interferon alfa 2b……....120mcg (Lyophilized powder for injection) (Anti viral anti proliferative Immunomodulator) Diluent to be supplied with each vial **(Local manufacture)**	0.5ml Rs.11,900/- per vial Diluent to be supplied free of cost and requires separate regsitration	Recommended
73.	Macter International Limited, Karachi , F-216, SITE, Karachi (API Import in concentrated bulk from M/s Intas Pharmaceuticals Ltd, India and local formulation and freeze-drying at M/s Macter International, F-216, SITE, Karachi)	**Peg-In Injection** 150mcg /0.5ml Each vial contains:- Pegylated rh-Interferon alfa 2b……150mcg (Lyophilized powder for injection) (Anti viral anti proliferative Immunomodulator) Diluent to be supplied with each vial **(Local manufacture)**	0.5ml Rs.14,875/- per vial Diluent to be supplied free of cost and requires separate regsitration	Recommended

74.	Macter International Limited, Karachi , F-216, SITE, Karachi (API Import in concentrated bulk from M/s Intas Pharmaceuticals Ltd, India and local formulation at M/s Macter International, F-216, SITE, Karachi)	**Neupeg** 6mg/ml Injection Each vial contains:- Pegfilgrastim ……..6mg (Immunomodulator) **(Local manufacture)**	1ml Rs.53,730/-	Recommended
75.	Macter International, Karachi. Labeled Vials imported from M/s. Beijing Shuanglu Pharmaceutical Co., China and local re-packing at M/s. Macter International, Karachi. (Import of labeled vials and local repacking)	**Prance Injection** Each vial contains: Recombinant Human Basic Fibroblast Growth Factor……35000 IU (Growth Factor). **(Local manufacture)**	Rs.1753 / Per vial	Recommended
76.	Macter International, Karachi. Import of labeled PFS from M/s. Beijing Shuanglu pharmaceutical Co., China and local re-packing at M/s. Macter International, Karachi.	**Macgrastim Injection** Pre-filled Syringe Each ml contains:- Filgrastim (rhG-CSF)…….300ug (Immunomodulator). **(Local manufacture)**	Rs.4375 /Per 300mcg pre-filled syringe.	Recommended

77.	**Hilton Pharma (Pvt)** Ltd., Karachi. Concentrate import from: M/s Nanogen Pharmaceutical Biotechnology Co., Ltd. Vietnam and local formulation and filling at Hilton Pharma (Pvt) Ltd., Karachi.	**Lameo** Injection 3 MIU Each vial contains:- Interferon alfa-2b…3 MIU (Lyophilized). (Recombinant Interferon) **(Local manufacture)**	As per PRC	Recommended
78.	Hilton Pharma (Pvt) Ltd., Karachi. Concentrate import from: M/s Nanogen Pharmaceutical Biotechnology Co., Ltd. Vietnam and local formulation and filling at Hilton Pharma (Pvt) Ltd., Karachi.	**Lameo** Injection 5 MIU Each vial contains:- Interferon alfa-2b…5 MIU (Lyophilized). **(Local manufacture)**	As per PRC	Recommended
79.	Hilton Pharma, Karachi Concentrate import from: M/s Biocon, Banglore. India formulation and filling at Hilton Pharma (Pvt) Ltd., Karachi.	**Xiro** Injection Each ml contains:- Filgrastim ……..300 ug **(Local manufacture)**		Recommended

Case No:04. Veterinary Vaccines.

Following veterinary drugs were deferred for further strain related comments for Pakistani market by the following experts. The committee will submit its report within 15 days to Directorate of Biological Drugs for consideration of Registration Board.

1. Prof Dr. Khushi Mohammad, UVAS, Lahore
2. Prof Dr. Masood Rabani, UVAS, Lahore
3. Dr. Arshad, Member DRB
4. Dr Manzoor, NVL/FAO project Islamabd.

S.No.	Applicant	Brand name and Specs	Price	ECBD
80.	M/s. Electrovet Pharma, Rawalpindi. M/s.CEVA-PHYLAXIA Veterinary Biologicals Co. Ltd. Budapest, Hungary.	**Cevac Transmune Live**, freeze-dried complex vaccine Infectious bursal disease virus (IBDV), Winterfield 2512, starin G-16……min. $10^{0.1}$ CID_{50} (Immunological Product). **(For Veterinary Use).**	Decontrolled 1000 doses 2000 doses 2500 doses 5000 doses 10000 doses	Recommended
81.	**M/s. Ghazi Brothers, Karachi.** M/s. IZO S.p.A., Via A. Bianchi 9, Brescia, Italy.	**Izovac Aviflu 9** Multidose Freeze-Dried Bottle Each dose of 0.5ml of vaccine contains:- Inactivated Avian Influenza A, strain H9N2……..320 H.A.U. (Immunological) **(For Veterinary Use).**	Decontrolled 250ml (500 doses) 500ml (1000 doses).	Recommended
82.	**M/s. Golden Harvest, Karachi.** M/s. Lohmann Animal Health International, Winslow, Maine, United State of America.	**AviPro ® 105 ND** Chick Vaccine Each per dose (0.1ml) contains:- Newcastle disease virus, B1 type, LaSota strain, (a minimum of 108.1 EID50 (Inactivated poultry vaccine). **(For Veterinary Use).**	Decontrolled 5000 doses/ 500ml	Receommended

83.	M/s. Golden Harvest, Karachi. M/s. Lohmann Animal Health International, Winslow, Maine, United State of America.	**AviPro ® 108 FC 3** PlatinumVaccine Each per dose (0.25ml) contains:- Pasteurella multocida, X-73 strain (Type 1)…….108.5 CFU Pasteurella multocida, P-1662 strain (Type 4)….108.5 CFU Pasteurella multocida, 86-1913 strain (Type 3x4)…108.5 CFU (Inactivated poultry vaccine). **(For Veterinary Use).**	Decontrolled 1000 doses/ 250ml	Receommended
84.	**M/s. Hilton Pharma** (Pvt) Ltd., Karachi. M/s. PT. MEDION JI. Raya Batujajar Cimareme, Kabupaten Bangdung, Indonesia.	**Medivac ND-Gumboro** Emulsion Vaccine Each dose (0.5ml) of vaccine contains:- Inactivated Newcastle disease virus of LaSota strain at least 50 PD50 Inactivated infectious bursal disease virus of Winterfield 2512 strain at least 800 serum neutralization (SN). **(For Veterinary Use).**	Decontrolled 500ml	Receommended
85.	**M/s. Hi-Tech** Pharmaceuticals, Lahore. Manufactured by: M/s. Pfizer Animal Health (Pfizer Inc), 2000 Rockford Road, Charles City, Iova, USA.	**Poulvac ® SE Vaccine** Each 0.5ml dose contains:- Salmonella enteritidis Phase Type 4……. …..RP….≥1.0/dose at release. Salmonella enteritidis Phase Type 8…RP…… …….≥1.0/dose at release. Salmonella enteritidis Phase Type 13a…RP…… …….≥1.0/dose at release. 37% Formaldehyde Solution……0.0006ml White Oil……0.1995ml Arlacel-83…..0.1105ml Tween-80…..0.00168ml Saline……q.s to 0.3ml **(For Veterinary Use).**	Not mentioned.	Recommended

86.	M/s. Hospital Services & Sales, Karachi. M/s. QYH (QIAN YUAN HAO) BIOLOGICAL CO. LTD., Beijing, P.R. China.	**QYH-ND IB EDS VAC** Each one dose contains:- Newcastle Disease, infectious Bronchitis & Egg Drop Syndrome Vaccine, Inactivated (La Sota Strain + M41 Strain + AV127 Strain). **(For Veterinary Use).**	Decontrolled 100ml/bottle 250ml/bottle 500ml/bottle	Defered for clarification on strain on virus incorpoarated in the vaccine
87.	M/s. Hospital Services & Sales, Karachi. M/s. QYH (QIAN YUAN HAO) BIOLOGICAL CO. LTD., Beijing, P.R. China.	**QYH-ND Live Vaccine** Each one dose contains:- Newcastle Disease Virus Sota Strain)HA titer of allanttoic fluids > 106.5 EID50/0.1ml before freeze drying. (Veterinary Vaccine). (For Veterinary Use).	Decontrolled 100ml/bottle 250ml/bottle 500ml/bottle	Recommended
88.	M/s. Huzaifa International, Sargodha. M/s. Komipharm International Co. Ltd., Korea.	**Pro-Vac ® ND * IB** Vaccine Each one dose contains:- Newcastle Disease virus (B1 straian,more than 107.5 EID50/ml, 40%)……more than 105.0 EID50 Infectious Broncchitis virus (KH-120 strain,nore than 105.5 EID50/ml,20%.....more than 102.5 EID50 LPGG……40% Streptomycin sulfate……..q.s Penicillin……q.s (Biological product (Live viral bivalent vaccine for Avian Infectious Bronchitis virus +Newcastle Disease virus). **(For Veterinary Use).**	Decontrolled 500 doses/vial 1000 doses/vial 2000 doses/vial 3000 doses/vial 5000 doses/vial	Recommended
89.	M/s. Huzaifa International, Sargodha. M/s. Kombipharm International Co. Ltd., Shihung-SI, Kyonggi-DO, Korea.	**Pro-Vac ® NDK** Vaccine Each one dose (0.5ml/dose) contains:- Inactivated Newcastle Disease virus culture solution……40% Formalin ……..0.1% Physiological Saline…..26.6% Aluminium Hydroxide Gel (50mg/1mL)…….33.3% (Vaccine). **(For Veterinary Use).**	Decontrolled 250ml 500ml 100ml	Recommended

90.	**M/s. Marush (Pvt) Limited, K-123, Model Town, Lahore.** M/s. Boehringer Ingelheim Vetmedica, S.A de C.V Guadalajara, Jal. Mexico.	**Barvac 10 Wayscon Retigen** Each 2.0ml dose contains:- Clostridium chauvoei……..1.2ml harvest with a minimum O.D. of 0.30 Clostridium septicum……15 CPU of toxoid Clostridium novyi……..10 CPU of toxoid Clostridium sordellii…….180 CPU of toxoid Clostridium perfringens….Type C 400 beta CPU of toxoid Clostridium perfringens….Type D 270 epsilon of toxoid Mannheimia haemolytica….1010 organisms Pasteurella multocida…..1010.2 organisms CPU = combining Power Units (Biological). **(For Veterinary Use).**	Decontrolled 25 doses/50ml 50 doses/100 ml	Recommended
91.	M/s. Marush (Pvt) Limited, K-123, Model Town, Lahore. M/s. Laboratorios Hipra S.A. Avda. La Selva Amer (Girona) Spain.	**Hipraviar-ND Broilers Injectable** Each per dose (0.2ml) contains:- Inactivated Newcastle Disease Virus, Strain La Sota……..> 108EID50 Adjuvant……q.s.ad.0.2ml (Biologicals). **(For Veterinary Use).**	Decontrolled 1000 doses 2500 doses	Recommended
92.	M/s. Marush (Pvt) Limited, K-123, Model Town, Lahore. M/s. Laboratorios Hipra S.A. Avda. La Selva Amer (Girona) Spain.	**Hipraviar-BPL2 Injectable** Each per dose (0.5ml) contains:- Inactivated Newcastle Disease Virus, Strain La Sota……HAI >…..1/16(*) *(*) IHA= Antibodies obtained using hemagglutination inhibition. (Biologicals). **(For Veterinary Use).**	Decontrolled 1000 doses 2500 doses	Recommended

93.	M/s. Marush (Pvt) Limited, Lahore. M/s. Laboratorios Hipra S.A. Avda. La Selva Amer (Girona) Spain.	**Coripracac Vaccine** Each dose of 0.5ml contains:- Haemophilus paragallinarum serotype A…….> 109 microorganisms Haemophilus paragallinarum serotype B…….> 109 microorganisms Haemophilus paragallinarum serotype C…….> 109 microorganisms (Biologicals). **(For Veterinary Use).**	Decontrolled 1000 doses	Receommended
94.	M/s. Marush (Pvt) Limited, Lahore. M/s. Laboratorios Hipra S.A. Avda. La Selva Amer (Girona) Spain.	**Hipragumboro-BPL2 Vaccine** Each dose of 0.5ml contains:- Inactivated Infectious Bursal Disease Virus, strain W2512…..….> 105 TCID50 Inactivated Newcastle Disease Virus, strain La Sota….> 108 EID50 Excipient q.s. ad…….0.5ml (Biologicals). **(For Veterinary Use).**	Decontrolled 1000 doses	Recommended
95.	M/s. Marush (Pvt) Limited, Lahore. M/s. Laboratorios Hipra S.A. Avda. La Selva Amer (Girona) Spain.	**Hiprapox Vaccine** Each dose contains:- Live Fowl-Pox Virus, strain FPV92……..> 104 EID50 Excipiants……q.s..ad.0.01ml (Biologicals). **(For Veterinary Use).**	Decontrolled 1000 doses	Recommended
96.	M/s. Marush (Pvt) Limited, Lahore. M/s. Laboratorios Hipra S.A. Avda. La Selva Amer (Girona) Spain.	**Hipraviar-BI/H120** Vaccine Each one dose contains:- Live Newcastle disease (ND) Virus, strain B1….> 106.5 EID50 Live infectious bronchitis (1B) Virus, strain H120….> 103EID50 (Biologicals). **(For Veterinary Use).**	Decontrolled 1000 doses 2000 doses	Recommended
97.	M/s. Marush (Pvt) Limited, K-123, Model Town, Lahore. M/s. CEVA-Biomune Veterinary Biologicals Company, Lenexa, KS USA.	**Vectormune HVT NDV** Injectable Each dose contains:- Marek's disease Newcastle disease antigen is at least 2280 PFU's per dose through expiration (Biological). **(For Veterinary Use).**	Decontrolled 1000 doses 2000 doses 4000 doses	Recommended

98.	M/s. Marush (Pvt) Limited, Lahore. M/s. CEVA-Biomune Veterinary Biologicals Company, Lenexa, KS USA.	**CEVAC MD RISPENS INJECTABLE** Each dose contains:- -Marek's Disease, Rispens CV 1988 Strain & Cryo No……..at least 2412 PFU per dose as release & at least 1608 PFU per dose through expiration. -Cryoprotectant No……..max 50% (Biological). **(For Veterinary Use).**	Decontrolled 1000 doses 2000 doses 4000 doses	Recommended
99.	M/s. Mustafa Brothers, Faisalabad. M/s. Federal Governmental Budgetary Institution "Federal Centre for Animal Health" (FGBI "ARRIAH", Vladimir, Russia.	**Dry Live vaccine** against Newcastle disease from strain La Sota. Contains:- One intranasal (ocular) dose of the vaccine contains at least 6.7 1g EID50/head of ND vaccine strain (strain La Sota) (Vaccine). **(For Veterinary Use).**	Decontrolled 400 doses	Receomended subject clarification of brand name
100.	**M/s. Selmore Agencies (Pvt) Ltd., Lahore.** M/s Dae Sung Microbiological Labs.Sam-Dong, Eiwang-Shi Kyunggi-Do, South Korea.	**ND+IB Killed VAC** Vaccine Each dose (0.5ml) contains:- Inactivated Newcastle BI or Lasota strain culture soup…20% Inactivated IB culture soup..15% (Vaccine). **(For Veterinary Use).**	Decontrolled 500 doses 1000 doses 2000 doses	Recommended
101.	M/s. Selmore Agencies (Pvt) Ltd., Lahore. M/s Dae Sung Microbiological Labs.Sam-Dong, Eiwang-Shi Kyunggi-Do, South Korea.	**EDS VAC Vaccine** Each dose (0.5ml) contains:- Inactivated EDS 76 culture…...15% (Vaccine). **(For Veterinary Use).**	Decontrolled 500 doses 1000 doses 2000 doses	Recommended

102.	**M/s. Snam Pharma, Lahore.** M/s. Bioveta a.s. Ivanovice na Hane, Czech Republic.	**Ornibur** Intermediate Plus, Lyophilizate for the preparation of suspension for domestic fowl Each one dose contains:- Virus bursitidis avium, strain IBDV OP-1, min. 104.0 TCID50-max.105.2 TCID50 (Vaccine). **(For Veterinary Use).**	Decontrolled 200 doses 500 doses 1000 doses 2500 doses 5000 doses 10 x 200 doses 10 x 500 doses 10 x 1000 doses 10 x 2500 doses 10 x 5000 doses	Recommended
103.	M/s. Snam Pharma, Lahore. M/s. Bioveta a.s. Ivanovice na Hane, Czech Republic.	**Ornimix Clone B1 + B120** Lyophilisate for preparation of suspension Each one dose contains:- Paramyxovirus pseudopestis avium, strain Bio 52: NDV B1-min. 106.0 EID50, max.107.5 EID50 Virus bronchitidis infectiosae avium, strain Bio 53: IBV H 120-min.103.0 EID50, max.104.8 EID50 (Vaccine). **(For Veterinary Use).**	Decontrolled 200 doses 500 doses 1000 doses 2500 doses 5000 doses 10 x 200 doses 10 x 500 doses 10 x 1000 doses 10 x 2500 doses 10 x 5000 doses	Recommended

104.	M/s. Vet Line International, Lahore. M/s.CEVA-PHYLAXIA Veterinary Biologicals Co. Ltd., Budapest, Hungary. Licence Holder:- M/s. Laprovet Hungary Veterinary Pharmaceutical LTd. Budapest, Hungary.	ITA ND + IBD Vaccine Each dose (0.5ml) contains:- Inactivated Newcastle disease virus, strain NDV-"SZ"… min…50 PD50 Inactivated Infectious Bursal disease virus, strain "GP" induced min..3 log10 VN (Biological-Avian inactivated Vaccine). **(For Veterinary Use).**	Decontrolled 500ml 1000 doses	Recommended
105.	M/s. Vet. Pharma Trading Company, Gujranwala. M/s. KBNP, INC, Dugok-ri, Sinam, Yesan, Chungnam, Korea.	**Himmvac ND Oil Vaccine** Each vial contains:- Inactivated ND virus (B1)…..30% (At least 108.8 EID50/dose) (Biological Products). **(For Veterinary Use).**	Decontrolled 500 doses 1000 doses	Recommended
106.	M/s. Vet. Pharma Trading Company, Gujranwala. M/s. KBNP, Inc. Dugok-ri, Sinam, Yesan, Chungnam, Korea.	**Himmvac Dalguban AN Oil Vaccine** Each per dose contains:- Low pathogenic AIV strain "A/Chicken/Korea/01310/2001 (H9N2)"….Min.108.5EID50 NDV strain "LaSota"……..Min. 109.5 EID50 **(Poultry Vaccine).**	Decontrolled 500 doses 1000 doses 2000 doses	Recommended

107.	M/s. Vet. Pharma Trading Company, New Steel Market, Near Regent Cinema, G.T. Road, Gujranwala-Pakistan. M/s. KBNP, Inc. Dugok-ri, Sinam, Yesan, Chungnam, Korea.	**Himmvac DHPPL Vaccine** Each Freeze-dried fraction: DHPP live vaccine per dose contains:- Freeze dried, Modified Live……25% Canine Distemper virus…..(at least 103.5 EID50/dose) Infectious Canine Hepatitis virus 25% ……(at least 105.0TCID50/dose). Canine Parainfluenza type 2 virus 30% (at least 104.0 TCID50/dose). **(Canine Vaccine)**	Decontrolled 10 dose 5 doses	Recommended
108.	M/s. Vety-Care (Pvt) Ltd., Rawalpindi. M/s. Intervet International, USA.	**Innovax-Nd Vaccine** Each dose contains:- Live Turkey Herpes Virus strain HVT/NDV-F>……at least 1810 PFU per bird dose. (Live virus vaccine) **(For Veterinary Use).**	Decontrolled 2000 doses	Recommended
109.	M/s. Vety-Care (Pvt) Ltd., Rawalpindi. M/s. Intervet International B.V. Wim de Korverstraat, AN Boxmeer, Netherland.	**Nobilis SG 9R Vacccine** Each dose 0.2ml contains:- Salmonella gallinarum strain 9R in stabilizer……at least 2x107 CFU (Live vaccine). **(For Veterinary Use).**	Decontrolled 1000 doses	Recommended

Case No: 05. Miscellaneous cases

A. M/s Martin Dow Limited, Karachi had applied for the registration of six biological products which were approved in the 237th DRB meeting and for which panel inspection was conduct by a panel consisting of Dr Uzar ul Ghani, Dr Najmus Saqib of the firm M/s Nanogen Biopharmaceuticals, Tang NhonPhua ward, Vietnam. The panel has submitted the report on 09.04.2013 and has recommended following products for registration:

S. No.	Product Brand Name	Generic name	Inspection Report Remarks
1.	PEGNANO, PFS	Peg Interferon alfa-2a 180 mcg	Good
2.	FERONSURE, PFS	Interferon alfa-2a 3MIU	Good
3.	FERONSURE, VIAL	Interferon alfa-2a 3 MIU	Good
4.	NANOKINE, PFS	Erythropoietin alfa, 4000 IU	Good
5.	FICOCYTE, PFS	Filgrastim, 30 mcg	Good
6.	PEGCYTE, PFS	Peg Filgrastim, 6 mg	Good

Decision of 238tyh meeting: Registration Board deferred above cases for confirmation of evaluation by ECBD.

ECBD: ECBD recommends the inspection report to be submitted for the approval in the DRB.

Decision: Keeping in view recommendations of ECBD in 45th meeting dated 23.06.2011 and 4th meeting dated 01.11.2013, Registration Board approved PEGNANO PFS and FERONSURE PFS for registration. Rest of items were deferred for consideration of ECBD.

Item No.VII Additional Agenda for 240th meeting Registration Board:

Case No. 01: Registration applications in which applicants are not interested further.

a. Human Drugs (Imported products).

The following applications are complete but firms have not dopsited the balance fee as per revised Fee schedule. They informed that they are not interested in processing of these applications. Submitted for the consideration of the Board.

S. #	Name of Applicant	Name of Drug(s)/Composition	Price/Pack Size	Shelf Life	Date of application receiving & Fee
1.	M/s. Bajwa Sons, Lahore. / M/s. Yancheng Huida Medical Instruments Co. Ltd, Jiangsu, China.	TruSteel Surgical Steel Wire (Surgical Suture)	As per PRC	05 years	04-05-2012 Rs.15000/-
2.	M/s. Bajwa Sons, Lahore. / M/s. Yancheng Huida Medical Instruments Co. Ltd, Jiangsu, China.	Trupolyester Polyester Braided Surgical Suture (Surgical Suture)	As per PRC	05 years	04-05-2012 Rs.15000/-
3.	M/s. Nishat Surgical Hyderabad Sindh Pakistan / M/s.Dogsan Tibbi Malzeme Sanayi A.S. Trabzon Turkey.	Daylon Non Absorbable Surgical Sutures with Needle (Medical Disposable Device)	List Attached (15 code)	05 years	26-03-2012 Rs.15000/-
4.	M/s. Nishat Surgical Hyderabad Sindh Pakistan / M/s.Dogsan Tibbi Malzeme Sanayi A.S. Trabzon Turkey.	Poilter Non Absorbable Surgical Sutures with Needle (Medical Disposable Device)	List Attached (11 code)	05 years	26-03-2012 Rs.15000/-

b. **Veterinary Drugs (Imported products).**

The following applications are complete but firms have not dopsited the balance fee as per revised Fee schedule. They informed that they are not interested in processing of these applications.

1.	M/s. Mustafa Brothers, Faisalabad. / M/s. LVL-Lebanese Veterinary Laboratories, Baabdat-EI Metn-Lebanon.	Enrotylo Oral Suspension Each ml of Enrotylo contains:- Enrofloxacin..100mg Tylosin Tartrate..50mg Vitamin C…80mg (A combination of fluoroquinolone Antibiotic, Macrolide Antibiotic and Vitamin C).	De-controlled 100ml 250ml 500ml 1000ml	03 years	26-03-2010 Rs.15000/-	M/s. Mustafa Brothers, Faisalabad is no more interested for their registration because the said manufacture has sold products to some other company.
2.	M/s. Mustafa Brothers, Faisalabad. / M/s. LVL-Lebanese Veterinary Laboratories, Baabdat-EI Metn-Lebanon.	Colidox Water Soluble Powder Each ml contains:- Doxycycline Hcl….100mg Colistine Sulfate (19000 IU/mg)…50mg (Antibacterial combination of tetracycline and cyclopeptide).	De-controlled 100g 500g 1 Kg	03 years	26-03-2010 Rs.15000/-	-Do-
3.	M/s. Mustafa Brothers, Faisalabad. / M/s. LVL-Lebanese Veterinary Laboratories, Baabdat-EI Metn-Lebanon.	Amerium Injectable Each ml contains:- Tetracycline…..15mg Oxytetracycline15mg Sulfadimerasol…50mg Hydrocortisone2.5mg Nicotinamide…25mg Vitamin C….10mg (Antibacterial + Vitamin).	De-controlled 20ml 50ml 100ml 250ml	03 years	26-03-2010 Rs.15000/-	-Do-
4.	M/s. Mustafa Brothers, Faisalabad. / M/s. LVL-Lebanese Veterinary Laboratories, Baabdat-EI Metn-Lebanon.	Labcox Oral Solution Each ml contains:- Toltrazuril……25mg (Coccidial).	De-controlled 100ml 250ml 500ml 1000ml	03 years	26-03-2010 Rs.15000/-	-Do-
5.	M/s. Mustafa Brothers, Faisalabad. / M/s. LVL-Lebanese Veterinary Laboratories, Baabdat-EI Metn-Lebanon.	Doxiline Oral Solution Each ml contains:- Doxycycline Hyclate….100mg (Antibacterial-Tetracycline).	De-controlled 100ml 250ml 500ml 1000ml	03 years	26-03-2010 Rs.15000/-	-Do-
6.	M/s. Mustafa	Nova Cefalex 15%	De-	02	Rs.15000/-	Defer

	Brothers, Faisalabad. / M/s. Nova Laboratories Sdn., Malaysia.	Injectable Oily Suspension. Each ml contains: - *Cefalexin…..…150mg* (Anti bacterial)	controlled 20ml 50ml 100ml 250ml	years		(M-236) meeting, the firm has not interested and not deposited the deferential fee.
7.	M/s. Mustafa Brothers, Faisalabad. / M/s. Nova Laboratories Sdn., Malaysia.	Novamox-G Injectable Oily Suspension. Each ml contains: - Amoxicillin as trihydrate.....150mg Gentamicin as sulfate….40mg (Anti bacterial)	De-controlled 20ml 50ml 100ml 250ml	02 years	Rs.15000/-	-Do-
8.	M/s. Mustafa Brothers Faisalabad. / M/s. Nova Laboratories Sungai Pelek, Sepang, Selangor Darul Ehsan Malaysia.	Sulfatrim 48% Oral Suspension Contains: - Sulfadiazine……400mg Trimethoprim……80mg (Antibacterial)	De-controlled 100ml 250ml 500ml 1000ml	2 years	Rs.15000/-	-Do-
9.	M/s. Mustafa Brothers Faisalabad. / M/s. Montajat Veterinary Pharmaceuticals Co., Ltd., 2nd Industrial City P.O.Box 4248, Dammam 31491 Kingdom of Saudi Arabia.	Ivermic-Oral- Oral Solution Each ml contains: - Ivermectin….0.8mg	De-controlled 100ml Bottle 250ml Bottle 500ml Bottle 1 liter Bottle 5 liter Bottle	36 months	Rs.15000/-	-Do-
10.	M/s. Mustafa Brothers Faisalabad. / M/s. Montajat Veterinary Pharmaceuticals Co., Ltd., 2nd Industrial City P.O.Box 4248, Dammam 31491 Kingdom of Saudi	Florjat Oral Solution Each ml contains: - *Florfenicol…..100mg*	De-controlled 100ml Bottle 250ml Bottle 500ml Bottle 1 liter	24 months	Rs.15000/-	-Do-

	Arabia.		Bottle 5 liter Bottle			
11.	M/s. Mustafa Brothers Faisalabad. / M/s. Montajat Veterinary Pharmaceuticals Co., Ltd., 2nd Industrial City P.O.Box 4248, Dammam 31491 Kingdom of Saudi Arabia.	Neojat Water Soluble Powder Each 1gm contains: - Neomycin Sulphate..1000mg	De-controlled 100 Sachet 250 Sachet 500 Sachet 1kg Tin Pack 5kg Bucket Bottles	36 months	Rs.15000/-	-Do-

Decsion: Registration Board acceded request of firm.

Case No: 02 Cancellation of Registration of Veterinary Injectables registered in the name of M/s. Avicenna Laboratories (Pvt) Ltd., Sheikhupura.

Federal Inspector of Drugs, Lahore conducted inspected of M/s. Avicenna Laboratories (Pvt) Ltd., Sheikhupura on 04-03-2013, wherein the FID has reported that the firm has registration of following (10) injaectable products including (Penicillin and Steroids) but the Injectable Section is not approved as yet by Licensing Section and the Registration Section has granted the registration of the same:-

S. No.	Reg. No.	Name of Drug (s) / composition.
1.	035001	Gentacen 100 Injectable Solution. Each ml Contains: - Gentamycin Sulphate (eq to 100mg Gentamycin base).
2.	035002	Moxicol Injectable Suspension. Each ml contains: - Amoxycillin Trihydrate 100mg. Colistin Sulphate 250,000 IU.
3.	035003	Avimox Injectable Suspension. Each ml contains: - Amoxycillin base (as trihydrate) 150mg.
4.	035004	Tylocen-200 Injectable Solution. Each ml contains: - Tylosin Sulphate 200mg.
5.	035005	Avoxy LA Injectable Suspension. Each ml contains: - Oxytetracycline HCl…200mg.
6.	035006	Dexon-5 Injectable Solution. Each ml contains: - Dexamethasone 5mg.
7.	035127	Oxytocen Injectable Solution. Each ml contains: - Oxytocin 10 I.U.
8.	043166	Predexon Injectable Suspension. Each ml contains:- Dexamethasone …… 2.5mg. Prednisolon …….. 7.5mg.
9.	043167	Lincospec Injectable Solution. Each ml contains:- Spectinomycin Sulphate 100mg base. Lincomycin Hydrochloride 50mg base.
10.	043168	Avigen-F20 Injectable Solution. Each ml contains:- Gentamycin Sulphate ……. 10mg. Flumequine …… 20mg.

Decision: The Board after detailed discussion decided that the production of the firm for above mentioned products should immediately be stopped till the complete investigation of the matter and issue a show cause notice to the firm for explanation of reasons in their defense. Then place the case before the board for further deliberations.

Case No.03: Epoch Pharmaceutical, Karachi.

Registration Board in its 238th meeting held on 5th & 6th August, 2013 deferred following registration applications of M/s Epoch Pharmaceuticals, Karachi for reason mentioned in last column.

S. No.	Name of Drug & Composition	Pack size	Demanded MRP	Decision
1.	Floroflox I.V Infusion 200mg/100ml Each 100ml contains:- Ciprofloxacin ..200mg (Anti Infective)	Per bottle	Rs.750.00	Deferred for product specific inspection by DDG, DRAP, Karachi, area FID and Director DTL, Quetta.
2.	Levosul Tablets 25mg Each tablet contains:- Levosulpiride ..25mg (Anti depressives)	Per tablet	Rs.7.50	-Do-
3.	E-Don Tablets 1mg Each film coated tablet contains:- Risperidone …….1mg	Per tablet	Rs.12.00	-Do-
4.	Roxet Tablets 20mg Each film coated tablet contains:- Paroxetine ……20mg (Anti depressants)	Per tablet	Rs.22.00	-Do-
5.	Citram Tablets 10mg Each film coated tablet contains:- Escitalopram as oxalate……10mg (Anti depressants)	Per tablet	Rs.16.42	-Do-
6.	Pentin Capsule 300mg Each capsule contains:- Gabapentin ……..300mg (Anti Epileptic)	Per capsule	Rs.15.00	-Do-

Now DDG (E&M), DRAP, Karachi has submitted inspection report dated 1st November, 2013 conducted by panel comprising Mr. Amanullah Khan Member, Registration Board / Director DTL, Quetta, DDG, DRAP and Mr. Abdul Rasool Shaikh, concerned FID, DRAP, Karachi. Panel of inspectors is of the opinion not to recommend the grant of above stated products registrations in the name of firm. Furthermore the panel also recommends that keeping in view the gross GMP violations their production in tablet, capsule and sterile injection areas should be suspended till the compliance of all critical observations.

Decision: The Board after detailed discussion decided to stop production of the firm immediately for products registered in tablet, capsule and injection dosage form and issue a show cause notice to the firm for suspension / cancellation of registration due to non-GMP compliance in aforementioned sections. Moreover, Registration Board rejected application for grant of registration of above 06 products due to non- GMP compliance as reported by the panel.

Case No.04: New License- M/s Pharma Health Pakistan (Pvt.) Ltd., Ferozepur Road Lahore

(i) Tablet Section (Hormonal)
(ii) Capsule Section (Hormonal)
(iii) Injectable Section (Hormonal)

Following applications of M/s. Pharma Health Pakistan (Pvt.) Ltd., Ferozepur Road Lahore were deferred for provision of source of active raw material in its 238th meeting of Drug Registration Board. The firm has submitted source of active raw material and confirms that all sources are of synthetic origin. These are neither natural nor of biological origin, even the method of analysis for such active ingredients is non-biological but is of chemical type. :-

S.No	Brand name/ Label claim	Pack size	Proposed price	Source of active ingredients	Nature of active ingredients	Remarks
1.	Folligon Injection Each ml contains:- Follitropin Beta … 50IU (Gonadotropins)	1's	Rs.1750/- per injection	Hangzhou Union Biotechnology Co., Ltd, China.	Synthetic Origin	
2.	Oxyto Injection Each ml contains:- Oxytocin ……..5IU	50's	Rs.7.50/-per injection	Hangzhou Huajin Pharmaceuticals Co., Ltd., China.	Synthetic Origin	
3.	Lyssa Depot Injection Each ml contains:- Testosterone Enanthate…..250mg (Androgen)	1's	Rs.40.83	ASG Biochem (Pvt.) Ltd, India	Synthetic Origin	Firm has provided two different certificates from different manufacturers. Certificate from M/s. Indo Phyto chemical India confirming that no animal origin is used during manufacturing of Testosterone Ethanthate and this material is

						never put in contact any time with a product of animal origin which is susceptible to TSE/BSE. Certificate from ASG Biochem India confirming that entire manufacturing sequence is free from BSE (Bovine Spongiform Encephalopathy and TSE (Transmissible Spongiform Encephalopathy) this material is manufactured totally by synthetic route and precursor material is not produced from any animal product.
4.	Zanziberon Injection Each ml contains:- Hydroxy progesterone caproate…..250mg Oestradiol valerate…….5mg	1's	Rs.78.16	Tianjin TianMao Technology Development Corp. Ltd., China.	Synthetic Origin	Firm has provided two different certificates from different manufacturers. Certificate from M/s. Indo Phyto chemical India confirming that no animal origin is used during manufacturing of Hydroxy progesterone caproate and this material is never put in contact any time in contact with a product of animal origin which is susceptible to TSE/BSE. Certificate from

						Lijiang Yinghua Biochemical China certifying that no animal material contained During the whole production process and also no raw materials are used which are generated from animal sources during production.
5.	Dupatox 10mg Tablets Each film coated tablet contains:- Dydrogesterone…10mg (Progestogen)	2 ×10's	Rs.25/- per tablet	Tianjin TianMao Technology Development Corp. Ltd., China.	Synthetic Origin	Certificate from Lijiang Yinghua Biochemical China certifying that no animal material contained During the whole production process and also no raw materials are used which are generated from animal sources during production.
6.	Steron 25mg Tablets Each tablet contains:- Mesterolone…25mg (Androgen)	2×10's	Rs.10.00/- per tab	Bayer Schering Pharma AG, Europe	Synthetic Origin	
7.	Norgest-V Tablet Each sugar coated tablet contains:- Estradiol valerate……2mg Norgestrel……0.5mg (estrogen/ progestogen)	10's	Rs.11.90/1's	Tianjin TianMao Technology Development Corp. Ltd., China.	Synthetic Origin	Certificate from M/s. Zhejiang Xianju Pharma China certifying that no animal material contained During the whole production process and also no raw materials are used which are generated from animal sources during production.
8.	Gynolon Tablet Each tablet contains:-	1×2's	Rs.13.73/per tab	Zhejiang Xianju Junye	Synthetic Origin	

	Methylestrenolone…..5mg Methyloestradiol…..0.3mg (oestrogen)			Pharmaceuticals Co., Ltd., China.		
9.	Jasmin Tablets Each tablet contains:- Ethynyloestradiol….0.02mg Gestodene……0.075mg (Cestrogen/Progestogen)	10's	Rs.16.67/ Per tab	Tianjin TianMao Technology Development Corp. Ltd., China.	Synthetic Origin	Certificate for Ethynylestradiol from M/s. Zhejiang Xianju Pharma China certifying that no animal material contained during the whole production process and also no raw materials are used which are generated from animal sources during production. BSE/TSE free Certificate from ASG Pharma India
10.	Cydin Tablet Each sugar coated tablet contains:- Estradiol valerate……2mg Cyproterone acetate……..1mg (Oestrogen/amto-amdrpgem)	10's	Rs.15.80/per tab	Tianjin Tian Mao Technology Development Corp. Ltd., China.	Synthetic Origin	Certificate from M/s. Zhejiang Xianju Pharma China certifying that no animal material contained During the whole production process and also no raw materials are used which are generated from animal sources during production. BSE/TSE free Certificate for Estradiol from ASG Pharma India
11.	Promin Tablet Each tablet contains:- Norethisterone……5mg	10's	Rs.1.79/per tab	Tianjin Tian Mao Technology Development Corp.Ltd., China.	Synthetic Origin	Certificate from M/s. Zhejiang Xianju Pharma China certifying that no animal material contained During the whole production process and also

						no raw materials are used which are generated from animal sources during production. BSE/TSE free Certificate from ASG Pharma India
12.	Fam 35 Tablet Each tablet contains:- Ethynyloestradiol….0.035mg Cyproterone acetate……2mg (Anti-androgen/oestrogen)	10's	Rs.11.71/per tab	Tianjin Tian Mao Technology Development Corp.Ltd., China.	Synthetic Origin	Certificate for Ethynylestradiol from M/s. Zhejiang Xianju Pharma China certifying that no animal material contained during the whole production process and also no raw materials are used which are generated from animal sources during production.
13.	Prometril Tablet Each tablet contains:- Lynestrenol…….5mg (Progestogen)	10's	Rs.5.83/ per tab	Zizhu Pharmaceutical Co., Ltd China	Synthetic Origin	BSE/TSE free Certificate from ASG Pharma India and IPC India.

Decision: Registration Board deferred for product specific inspection for confirmation of manufacturing and quality control facilities by panel comprising of Director, DTL, Lahore and area FID.

Case No 05: APPLICATIONS FOR REGISTRATION OF MEDICAL DEVICES FOR IMPORT.

The Registration Board considered the following applications of medical devices and decided as mentioned against each. Approved applications have already been recommended by Expert Committee on Medical Devices and are subject to inspection of manufacturer abroad, verification of storage facilities etc as per policy.

A: CATHETERS

S.No.	Name of Importer and Manufacturer/Exporter.	Name of Medical Device.	Demanded price & Pack size	Shelf life	Decision
1.	M/s Johnson & Johnson (Pvt) Ltd, Plot.No.10 & 25, Sector 20, Korangi Industrial Area, Karachi. **Legal Manufacturer** M/s Codman & Shurtleff, Inc. 325 Paramount Drive Raynham, MA, USA. **Assembler:** M/s Codman & Shurtleff. Calle Cirrcuito Interior Norte No.1820, Parque Industrial Salvarcar, Ciudid Juarez, Chihuaha, CP 32575, Mexico. M/s Cordis de Mexico SA de C.V. Calle Cirrcuito Interior Norte No.1820, Parque Industrial Salvarcar, Ciudid Juarez, Chihuaha, CP 32575, Mexico.	Prowler Micro Catheters - Prowler Select LP-ES - Prowler Select Plus - Prowler 10 - Prowler 14 - Prowler Plus (Micro Catheters)	Decontrolled (Different product sizes and codes available as provided in registration dossier)	3 years	**Approved**

B: CANULAS

S.No.	Name of Importer and Manufacturer/Exporter.	Name of Medical Device	Demanded price & Pack size	Shelf life	Decision
1.	M/s Mana & Co, 204 New Medicine Market, Near Densohall, Karachi. **Manufactured by** M/s Jiangxi Huali Medical Instrument Co.Ltd. Yudu Industrial Zone,Ganzhou, Jiangxi, China.	Medicare IV Catheter with Injection Port.	Decontrolled (14G, 16G, 18G, 20G, 22G, 24G)	5 years	**Rejected** due to incomplete and unsatisfactory stability profile.

C: SYRINGES

S.No.	Name of Importer and Manufacturer/Exporter.	Name of Medical Device	Demanded price & Pack size	Shelf life	Decision
1.	M/s Becton Dickinson Pakistan (Pvt) Ltd, 19-D/1, Gulberg-III, Lahore. **Manufactured by:** M/s Becton Dickinson Medical (S) Pte Ltd, 30 Tuas Avenue 2, Singapore 639461, Singapore.	BD ™ Syringe Slip Tip with BD Precision Glide ™ Needle (24G, 25G, 26G, 27G)	Decontrolled 1ml	5 years	**Deferred for the provision of samples.**

Case No.15. Miscellaneous cases.

Case No.a. Draft Medical Device Rules, 2013

During the previous meeting of Registration Board, the members were informed that the draft Medical Device Rules, 2013 have been uploaded on the website of DRAP (www.dra.gov.pk) and were requested to please furnish their comments. As comments from the members have not been received, meaning that the Registration Board agrees to the draft Medical Device Rules, 2013.

Decision: Chairman of the Board advised its members to submit the comments on draft Medical Device Rules, 2013 to Directorate of Medical Device & Medicated Cosmetics prior to next meeting of Registration Board.

Case No.b. Relaxation in the condition of the Drug (Labeling & Packaging) Rules, 1986

M/s Johnson & Johnson Pakistan (Pvt) Ltd, Karachi was granted permission for import of below mentioned medical devices in international packs and to print Urdu version, registration number and MRP through lazer jet printing at their licensed premises before marketing on 7th November, 2012 for the period of one year:-

(i) Cordis Catheters (Diagnostic & Guiding) Reg. No.071628
(ii) Palmaz Genesis Stent Reg. No.071629
(iii) SES Precise RX Stent Reg. No.071630

The firm has requested for extension in permission of relaxation in condition of the Drug (Labeling & Packaging) Rules, 1986 i.e. Urdu version, Pak Registration Number and MRP of their above mentioned medical devices on same terms and conditions. The firm has deposited the fee of Rs.5000/- for each product. The firm has further submitted that Cordis diagnostic catheters and stents are the most trustworthy range by healthcare physicians for cardiac

catheterization as they are indicated for the delivery of interventional devices to coronary or peripheral Vascular systems during various cardiac surgeries and interventional procedures such as coronary angioplasty, reform carotid artery stenting as an option for patients at high risk for surgeries.

The firm has requested on the grounds that the above mentioned products are being imported and utilized in Pakistan in a limited quantity for Pakistani Cardiac patients (average less than 2% in ratio of global supply is being imported in Pakistan) and minimum order quantities do not have the sufficient volume to make it viable for principal manufacturer to provide us country specific packs of the respective products.

Decision: Registration Board granted permission to M/s Johnson & Johnson Pakistan (Pvt) Ltd, Karachi for import of Cordis Catheters (Diagnostic & Guiding) (Reg. No.071628), Palmaz Genesis Stent (Reg. No.071629) and SES Precise RX Stent (Reg. No.071630) in international packs and to print Urdu version, Pak Registration Number and MRP through laser jet printing at their licensed premises at plot No. 10, Sector 20, Korangi Insustrial Area, Karachi before marketing these medical devices for the period of one year.

Case No.c. Relaxation in the condition of the Drug (Labeling & Packaging) Rules, 1986.

M/s Johnson & Johnson Pakistan (Pvt) Ltd, Karachi has requested for relaxation in condition of the Drug (Labeling & Packaging) Rules, 1986 i.e. Urdu version, Pak Registration Number and MRP of their already registered imported S.M.A.R.T Control Nitinol Stent System (Registration No.074662). The firm has deposited the fee of Rs.5000/-.

The firm has submitted that the S.M.A.R.T Control Nitinol Stent System belongs to sterile sensitive class of medical devices and is supplied in Sterile Peel Open Package after carrying out all recommended package integrity and sterility validation tests. To ensure the sterility of product till it is received by key user, packaging qualification testing is performed on the S.M.A.R.T. Control Nitinol Stent System which are packaged in a performed tray, sealed in packaging pouch and placed in a folding carton. The same sterilized pack is then supplied to all countries.

The firm has further submitted that as the product is being imported in Pakistan in a limited quantity for Pakistani patients (less than 1% in ratio of global supply is projected consumption for Pakistan) and minimum order quantities does not have the sufficient volume to

make it viable for principal manufacturer to provide country specific packs of the product. Therefore, the firm has requested for one of the following approval:-

1. to import S.M.A.R.T. Control Nitinol Stent System in international packs and then ink jet printing of urdu version, Pak Registration No. and maximum retail price at their locally licensed premises before market

OR

2. to fix the sticker having the above mentioned information on these devices before import into Pakistan.

Decision: **Registration Board granted the permission to M/s Johnson & Johnson Pakistan (Pvt) Ltd, Karachi for import of S.M.A.R.T Control Nitinol Stent System (Reg No.074662) in international packs and to print Urdu version, Pak Registration Number and MRP through laser jet printing at their licensed premises before marketing for period of one year.**

Case No.d. **COMPLAINT REGARDING MEDICAL DEVICES MANUFACTURED BY M/S MORNINGSIDE PHARMACEUTICAL LTD, UK IMPORTED BY M/S ELATE CC (PVT) LTD, KARACHI.**

The following medical devices (syringes and IV cannulas) were registered in the name of M/s Elate CC Pvt Ltd, Suit No.1,2,3, Block-3, Gulshan-e-Iqbal, Karachi. The products were approved in 226th meeting of Registration Board:-

S.No.	Reg. No.	Name of drug (s) & Composition.	Packing	Manufactured by
1.	066028	Sensecure 1ml Syringe.	1ml	M/s. Morningside Pharmaceutical Ltd., UK
2.	066029	Sensecure 3ml Syringe.	3ml	-do-
3.	066030	Sensecure 5ml Syringe.	5ml	-do-
4.	066031	Sensecure 10ml Syringe.	10ml	-do-
5.	066032	Sensecure 20ml Syringe.	20ml	-do-
6.	066033	Sensecure 30ml Syringe.	30ml	-do-
7.	066034	Sensecure 50ml Syringe.	50ml	-do-
8.	066035	Sensecure 60ml Syringe.	60ml	-do-
9.	066036	Sensecure IV Cannula 18 G.	18 G/	-do-

			pack of 100's.	
10.	066037	Sensecure IV Cannula 24 G.	24 G/ pack of 100's.	-do-
11.	066038	Sensecure IV Cannula 22 G.	22 G/ pack of 100's.	-do-
12.	066039	Sensecure IV Cannula 20 G.	20 G/ pack of 100's.	-do-

A complaint has been received in the DRAP which is a copy of email alongwith quotation of M/s Morningside Pharmaceutical Ltd, 5 Pavilion way, castle business park, Loughborough, Leicestershire, UK. The quotation is of different types of cannulas with brand name of Sensecure ® Morningside UK. The origin of IV cannulas mentioned in the quotation is India and the license mentioned is Wholesale Dealers License No.WL/22920/1.

In this regard, the official website of Medicines and Healthcare Products Regulatory Agency (MHRA), UK (Regulating Medicines and Medical Devices) has been checked.

(i) The **medical device register** which has database of registered devices does not show any registration of medical device of M/s Morningside Pharmaceutical Ltd, UK, being manufacturer.

(ii) **MHRA Register of Licensed Manufacturing Sites** (Human & Veterinary Sites) shows two manufacturing sites (Site ID: 37167 and Site ID: 393217) of M/s Morningside Pharmaceutical Ltd, UK (Manufacturer's Authorization No.UK MIA 22920) but the scope of manufacturer's authorization is for human medicinal products.

(iii) **MHRA Register of Licensed Wholesale Dealer Sites** (Human, Veterinary and Combined Sites) shows two wholesale sites (Site ID: 37167 and Site ID: 393217) of M/s Morningside Pharmaceutical Ltd, UK.

Decision: Registration Board after detailed discussion decided that M/s Elate CC Pvt Ltd, Suit No.1,2,3, Block-3, Gulshan-e-Iqbal, Karachi should be asked to clarify status regarding manufacturing of above mentioned medical devices by M/s. Morningside Pharmaceutical Ltd., UK and status of registration of these devices with MHRA, UK.

Registration Board deferred rest of items due to paucity of time.

Dr. Obaid Ulah

Digitally signed by Dr. Obaid Ulah
DN: cn=Dr. Obaid Ulah, o=Drug Registration Board, ou=Secretary, email=obaiddr@yahoo.com, c=PK
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