



PURCHASE CELL

DIRECTORATE GENERAL HEALTH
SERVICES PUNJAB
24-COOPER ROAD, LAHORE



Primary & Secondary
Healthcare Department

Phone No.: [+924299201145](tel:+924299201145)

Purchase Cell E-mail: pcdghslahore@gmail.com

MINUTES OF MEETING OF THE GRIEVANCE REDRESSAL COMMITTEE HELD ON 17th FEBRUARY, 2021 AT 02:00 P.M TO REDRESS THE GRIEVANCE APPLICATIONS OF THE FIRMS AGAINST TECHNICAL EVALUATION REPORT FOR THE PROCUREMENT OF DRUGS/MEDICINES (INSULIN-70/30, INSULIN-R AND INSULIN-N), FY 2020-21

A meeting of the Grievance Redressal Committee was held on 17th Feb, 2021 at 02:00 P.M in committee room of Directorate General Health Services, Punjab, to address the grievances of the applicants, as per Rule 67 of Punjab Procurement Rules, 2014 (Amended), for Procurement of Drugs/Medicines (INSULIN-70/30, INSULIN-R AND INSULIN-N), Directorate General Health Services, Punjab, FY 2020-21.

Following members of Grievance Redressal Committee attended the meeting:

| Sr. No. | Participants | |
|---------|---|--------------------------|
| 1. | Director Health Services (EPI), O/o DGHS | Chairman/Convener |
| 2. | Director Health Services (CD&EPC), O/o DGHS | Member |
| 3. | Senior Law Officer (Litigation Cell), O/o DGHS | Member |
| 4. | Additional Director Health Services (Medical), O/o DGHS | Member |
| 5. | Director Health Services (MIS), O/o DGHS | Member |

Following member(s) of the Technical Evaluation Committee presented the cases on behalf of the Technical Evaluation Committee:

| Sr. No. | Member(s) |
|---------|------------------------------------|
| 1. | Deputy Director Pharmacy, O/o DGHS |

The Chair welcomed all the participants and briefed about agenda of meeting i.e. Grievance Redressal of firms against Technical Evaluation Report. The Chair instructed the representatives of aggrieved firms to come one by one serial wise based on receipt of grievance so that proper hearing/ redressal of grievance may be ensured. The grievances of firms and decisions of grievance redressal committee are as follow:

| Sr. | Name of Firm | Name of Item | Reason(s) of Rejection | Grievance of the Firm | Decision of the Committee |
|-----|-----------------------------|--|---|--|---|
| 1 | M/s Getz Pharma (Pvt.) Ltd. | Insulin comp 70/30 Injection 100 IU/ml | Firm has attached bio similarity study of Insugen 30/70 manufactured by Biocon Limited, India, instead of its quoted product i.e. Insuget 70/30 | The firm submitted its grievance stating that our products, Insuget 70/30, Insuget-R and Insuget-N (Human Insulin) Injection 100IU/mL are technology transferred product from Biocon Ltd, India which conducted biosimilar studies on the above products before transferring the technology to Getz Pharma. It may be noted that Biocon Ltd. India is US-FDA approved manufacturer and one of the leading manufacturers of Biosimilar products in the world. The drug substance e Human Insulin (rDNA origin), used in the above products, is also manufactured by Biocon td. India, which is based on recombinant DNA technology Further, physiochemical and biological comparison of above Insuget range with RBP has been conducted during product development and technology transfer and the results were found well within specified (Phr. Eur.) Limits. In addition, finished products samples of Insuget 70/30. Insuget-R and Insuget-N were again shipped to Biocon's USFDA approved facility for testing purpose and results complied with the specifications Regarding conditions stated in point v.' of the Tender conditions please note that Getz Plants has already submitted the bio-similarity studies and analytical reports to ensure safety, efficacy and quality of said lifesaving | Mr. Ghulam Dastgir from M/S Getz pharma attended the meeting and presented their grievance to the Grievance Redressal Committee. The committee heard the viewpoint of the firm which was examined in light of Technical Evaluation Report. The committee after due deliberation and discussion, keeping in view the required parameters in detail, decided that M/S Getz pharma submitted bio similarity report/clinical study report conducted by Profil Institut für Stoffwechselforschung GmbH Hellersbergstraße 9 sponsored by Biocon Ltd, India which was conducted for finished product i.e. Insugen 30/70 manufactured by Biocon Ltd, India. However, firm quoted product is Insuget 70/30 which could not be acceptable against the advertised criteria of bidding document i.e. <i>"The firm will submit Bio similarity studies data of quoted item (for biologicals and biotech products)"</i> . Moreover, the same matter was decided by Honorable Lahore High Court Vide WP No. 4676/2021 and WP No. 7020/2020. In both these petitions M/S Getz pharma |
| 2 | M/s Getz Pharma (Pvt.) Ltd. | Insulin NPH Injection 100 IU/ml | Firm has attached bio similarity study of Insugen N manufactured by Biocon Limited, India, instead of its quoted product i.e. Insuget-N | | |
| 3 | M/s Getz Pharma (Pvt.) Ltd. | Insulin Regular Injection 100 IU/ml | Firm has attached bio similarity study of Insugen R manufactured by Biocon Limited, India, instead of its quoted product i.e. Insuget-R | | |

| Sr. | Name of Firm | Name of Item | Reason(s) of Rejection | Grievance of the Firm | Decision of the Committee |
|-----|--------------|--------------|------------------------|---|---|
| | | | | <p>drugs, as explained in the preceding paragraph</p> <ul style="list-style-type: none"> It is also important to note that Getz Pharma is the only local manufacturer whose Quality Management System is approved by WHO and PIC/S. which ensures that all products ii manufactured by Getz Pharma meet the highest quality standards. Besides, the safety, efficacy and quality of Getz Pharma's Insuget products can also be authenticated from the fact that it has been supplying these products in major Teaching Hospitals as per awarded contracts throughout in Pakistan and after detailed analysis by DTLs distributing to diabetic patients Getz Pharma Human Insulin Injections are registered with DRAP (Drug Regulatory Authority of Pakistan) and tested at Biocon's USFDA approved facility Copies of awards and orders attached. r That the Products sought to be procured i e. Insuget range is subject to exclusive regulatory 0 control of the Drug Regulatory Authority of Pakistan It is essentially jurisdiction of the DRAP 1 to develop. adopt and enforce the standards and guidelines to ensure safety, efficacy and quality of the drugs with rational use at reasonable price as evident from perusal of Section 7(0 of the DRAP Act 2012 The regulatory requirements under the DRAP Act 2012 and the Drugs Act 1976 and the rules made thereunder have | <p>assailed above mentioned bidding clause and Honorable Court dismissed the same.</p> <p>The grievance of M/S Getz pharma against M/S Novo Nordisk was examined and it has been found that M/S Getz pharma have taken same plea in writ petitions Vide WP No. 4676/2021 and WP No. 7020/2020 which were dismissed by Honorable Court. Furthermore, M/S Novo Nordisk also submitted valid COPP (Certificate of Pharmaceutical Product) issued by European medicine agency (EMA) clearly stated Mixtard 30 and Mixtard 30 HM are same products. Hence, grievance of M/S Getz pharma was rejected and status of its quoted product will remain "Nonresponsive".</p> |

| Sr. | Name of Firm | Name of Item | Reason(s) of Rejection | Grievance of the Firm | Decision of the Committee |
|-----|--------------|--------------|------------------------|---|---------------------------|
| | | | | <p>been satisfied by Getz Pharma whose Insuget products have been registered since 2008, for lawful sale in the private and public sectors and meet the standards of safety and efficacy prescribed by DRAP, hence cannot be excluded from consideration for public procurement, and any such exclusion will be manifestly arbitrary, violative of Articles 4, 18 and 25 of the Constitution of Pakistan. It may be pertinent to emphasize that the DGHS Punjab has procured Insuget in 2016/2017 without any reported complaint whatsoever as to the safety, efficacy or quality of the drug. From perusal of the list of prequalified firms, it is manifest that M/s Novo Nordisk has been prequalified in relation to its product namely Mixtard 30 HM, which does not meet the mandatory condition of bio-similarity studies data for the quoted item. Despite not fulfilling the aforementioned mandatory requirement, tender was awarded to them last year while arbitrarily a. without lawful authority relaxing the condition for them on the pretext that theirs was an Originator's product registered with FDA and EMA hence no bio-similarity study was required. Although certificates were issued to Novo Nordisk by FDA and EMA for Pakistan in relation to the product having registered trade names of Novolin and Mixtard 30 respectively, however, no such</p> | |

| Sr. | Name of Firm | Name of Item | Reason(s) of Rejection | Grievance of the Firm | Decision of the Committee |
|-----|--------------|--------------|------------------------|--|---------------------------|
| | | | | <p>certificate was issued or produced for the quoted item namely Mixtard 30 HM. Even this year, Mixtard 30 HM fails to satisfy the aforementioned mandatory requirement.</p> <p>We therefore hope and trust that DGHS Punjab authority will ensure a transparent and fair tender qualification process and avoid any action which discriminates amongst the bidders.</p> | |