PURCHASE CELL

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MINUTES OF MEETING OF THE GRIEVANCE REDRESSAL COMMITTEE MEETING HELD ON 30TH JANUARY 2020 AT 11.00 A.M IN COMPLIANCE TO ORDER DATED 29/1/2019 IN WRIT PETITION NO. 5056/20 BY HONOURABLE LAHORE HIGHCOURT, LAHORE

A meeting of the Grievance Redressal Committee was held on 30-01-2020 at 11.00 A.M in committee room of Directorate General Health Services, Punjab, to address the grievances of the M/s Getz Pharma Private Limited, in compliance to Honorable Lahore High court order dated 29-01-2020 in W.P. No. 5056/2020, for Procurement of Insulin 70/30 in RFP/Bidding of pharmaceutical manufacturers & sole agents of foreign principles for purchase of drugs/medicines for FY 2019-2020 Phase-II. Following members of Grievance Redressal Committee attended the meeting:

Sr. No.	Participants	
1.	Director Health Services CD & EPC, DGHS	**Chairman/Convener**
2.	Director Pharmacy, DGHS	**Member**
3.	Senior Law Officer, DGHS	**Member**

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

Sr. No.	Member(s)
1.	Additional Director Health Services Stats (MIS), DGHS
2.	Tender Coordination Officer-I, P&SHD
3.	Pharmacist M&E, DGHS

The Chair welcomed the participants and briefed about agenda of meeting. The grievances of firm and decision of the grievance redressal committee made thereof is as follow:

Name of Firm	Name of Item quoted by the firm	GREVIANCE OF THE FIRM	DECISIONS OF THE GREVIANCE COMMITTE
M/s Getz Pharma Private Limited	Insuget 70/30	Getz Pharma Private Limited is the second largest pharmaceutical company of Pakistan and is the leading exporter of Pharmaceuticals from Pakistan. The company has consecutively been awarded FPCCI Export Trophy from the President and Prime Minister of Pakistan for the last Fourteen years. Reviewing your technical evaluation report RFP Phase II uploaded on Primary and Secondary Health Care Department Website Dated December 24, 2019 that T.E No.4 is non responsive We request you to pleas revisit the assessment of items T.E No.4 (Injection Insuget 70/30) on the following grounds. Undertaking regarding "Non-Declaration of any Spurious/Adulterated Batch of quoted item by DTLs of the Punjab/any competent Lab" on valid Rs.100 duly notarized stamp paper was attached at page # 214 in bidding documents. However we are attaching again for your review. Experience of the quoted product since January 2018 till closing date of RFP submission in private sector is attached at page No.232. We were given zero marks while our sales of 810416 units during the required duration gives us 3 marks according to the bidding documents. (Copy attached) Experience of the quoted product since January 2018 till closing date of RFP submission in public sector is attached at page No. 233 to 305. We were given zero marks instead of 3 according to	Grievance regarding Undertaking of "Non-Declaration of any Spurious/Adulterated Batch of quoted item by DTLs of the Punjab/any competent Lab have already been decided in grievance redressal meeting dated 14-1-2020. Grievance regarding "Experience of the quoted product in private sector have already been decided in grievance redressal meeting dated 14-1-2020. Grievance regarding "Experience of the quoted product in public sector" have already been decided in grievance redressal meeting dated 14-1-2020. Grievance regarding "Credibility & Certification of Manufacturer section. Valid ISO 14001, WHO and PIC/s certifications" have already been decided in grievance redressal meeting dated 14-1-2020. Grievance regarding 17 stability chambers and required documents have already been decided in grievance redressal meeting dated 14-1-2020 Grievance regarding Real Time Stability Studies have already been decided in grievance redressal meeting dated 14-1-2020. Grievance regarding Primary Reference Standard have already been decided in grievance redressal meeting dated 14-1-2020.

		evaluation criteria we deserve 3 marks. (Copy attached) Credibility & Certification of Manufacturer section. Valid ISO 14001, WHO and PIC/s certifications are attached at Page No.306 to 342. We were given zero marks while we deserve 6 marks 3 for ISO 14001 and 3 for WHO/PICs certifications. (Copy attached) Getz Pharma Private Limited have 17 stability chambers and required documents are attached at Page No.344 to 355 in the bid. We deserve 6 marks while zero marks are awarded to us. (Copy attached) Accelerated and Real Time Stability Studies are attached at page No.364 to 368 in the bid we deserve 2 marks but zero marks were given to us. (Copy attached) Primary Reference Standard with Valid Shelf Life used for Quality Control Testing/Analysis of Quoted Item are attached at page No.365-370. Hence Getz Pharma Private Limited deserve 2 marks but zero marks given to us. (Copy attached) Getz Pharma Private Limited has attached two Biosimilar Studies from Page No.450 to Page No.609 in the bid while in the evaluation report it is stated that no biosimilar study is attached. 1-Cross-sectional survey of biosimilar insulin utilization in Asia: Published in JDI from Page No. 450-462. 2- Biosimilar Study in India from Page No. 463-542 3- Biosimilar Study in Germany Page No. 544-609 We are again attaching for your reference	Grievance regarding submission of 1- Biosimilar Study in India 2- Biosimilar Study in Germany 3- Cross-sectional survey of biosimilar insulin utilization in Asia: Published in JDI have already been decided in grievance redressal meeting dated 14-1-2020. Furthermore, during the course of meeting dated 30/1/2020 representative of firm himself admitted that they did not have the biosimilar study of their quoted product i.e Insuget 70/30 and they did not want to press the grievance regarding submission of Cross-sectional survey of biosimilar insulin utilization in Asia: Published in JDI. Grievance of the firm regarding violation of rule 26(2) could not be accepted because Prequalification was advertised for local manufacturer units and sole agents and not for international bidders. Neither the aggrieved firm namely M/s Getz Pharma Private Limited nor the responsive firm M/s Novo Nordisk Pharma (Pvt) Ltd Karachi Pakistan (bearing NTN 25352415) fall in the category of international bidders therefore rule 26(2) is equally applicable for both bidders hence grievance of the firm is rejected in this regard. Grievance regarding Minutes for 278th Meeting of Registration Board (29-31st January 2018), DRAP for Biological drugs using rDNA technology have already been decided in grievance redressal meeting dated 14-1-2020.

		We are the only local manufacturer of Insulin Injection (Insuget) and our facility is PIC/s & WHO approved which are International Bodies recognized all over the world. I can proudly say that we are the only company in Pakistan to have these certifications, as no other company is PIC/s/WHO certified locally. According to Rule 26(2) A procuring agency shall allow for a preference to domestic or national contractor in accordance with the policies of the Government and the magnitude of price preference to be accorded shall be clearly mentioned in the bidding document under the bid evaluation criteria in spite of according of preference to M/s Getz Pharma, a national pharmaceutical manufacturer, its product Insuget was knocked down even submission of Bio-Similar studies. (Copy attached). Minutes for 278th Meeting of Registration Board (29-31st January, 2018), DRAP for Biological drugs using rDNA technology states ‘’The firm shall provide the complete Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill) manufactured either from country of origin or by any reference regulatory authority as adopted by Registration Board to demonstrate the bio-similarity”. And Getz Pharma Private Limited provided the Two Biosimilar studies from Biocon since drug substance i.e. Human Insulin (rDNA origin) used for the manufacture of Insuget is of Biocon Ltd, India.	Grievance regarding complete technology transfer aggrieved firm provided reference document of US-FDA Scale Up and Post Approval Changes (SUPAC) - Site Changes Level 3 which pertains to Immediate release solid oral dosage form which does not include biotech items like insuget hence the evidence of the claim of complete technology transfer regarding the subject matter i.e Insulin is not substantiated and grieved firms additional claims in this regard are vague. Hence grievance of the firm is rejected. Grievance regarding firm evaluation sole agent at S. No. 1 T.E No.4 have already been decided in grievance redressal meeting dated 14-1-2020. Director General Health Services Punjab conducted prequalification on behalf of District Health Authorities (DHAs) and Provincial Control Programs. Anti -TB drugs at S.No. 299, 300 and 301 are specific subject and Provincial TB Program (end user) submitted their demand with their Technical specification. Moreover, Bioequivalence as per decisions of the meetings of experts held by procurement committees on dated 15-08-2014 & 10-08-2016 moreover, a letter was also issued by Health Department on 19-11-2014 in this regard which categorically stated that the condition of availability of bioavailability / bioequivalence study cannot be waived off for Anti TB drugs (Letter Ref # NO. SO (P-1) H/9-14/2012 Dated 19-11-2014.) Moreover, publication of bioavailability / bioequivalence studies on WHO website was also mandatory in specification of Anti T.B medicines. It is

		Clinical Trials Report was performed according to ICH, GCP by Clinigene International Pvt. Ltd., Bangalore. Registration Board of Drug Regulatory Authority of Pakistan (DRAP) after implementation of Biosimilarity Guidelines have granted approvals to the applicants/companies for change in manufacturing site without conducting Biosimilarity Study again from the new manufacturing site. (list and decisions attached) In reference to the Insuget Injections manufactured by Getz Pharma (Pvt.) Limited, the complete technology transfer of Insuget Injection was carried out from Biocon Limited India to Getz Pharma, which is one of global giant in biosimilar products. In addition to that, Active Pharmaceutical Ingredient used in the manufacturing Insuget Injections is still imported from Biocon Limited. Therefore, all the clinical studies performed by Biocon Limited are applicable on Insuget Injections, since it has same formulation, manufacturing process, specification and even source of API is same. (Documents already submitted, attaching again for review) Similarly, in accordance with US-FDA Scale Up and Post Approval Changes (SUPAC) - Site Changes Level 3 states,''Site changes consist of changes in location of the site of manufacture' there is no requirement of in-vivo Bioequivalence / Bio similarity studies again''. Therefore, all the clinical studies performed by Biocon Limited is applicable on Insuget Injections (copy attached). Dear Sir, We are also aggrieved by the firm evaluation sole agent at S. No. 1 T.E No.4 which is also not an	pertinent to mention here that condition of publication of bioavailability / bioequivalence on WHO website is very specific condition which is only laid down for Anti T.B drugs in prequalification document item list. Hence, these facts are evident that anti-TB drugs are very specific subject and have stringent criteria requirement as per recommendation of committee of experts. M/s Getz grievance regarding comparison of specification of specific condition of Anti T. B medicine with insulin have no grounds to substantiate. PPR2014 defines prequalification as procedure for demonstrating qualifications as a precondition for being inviting to tender. Qualification to determine in prequalification process as per PPR 2014, Rule16 are as follows: *(3) For purposes of the prequalification of bidders, a procuring agency shall take into consideration the following factors:* *(a) qualifications;* *(b) relevant experience and past performance;* *(c)capabilities with respect to personnel, equipment, and plant;* *(d) financial position;* *(e) appropriate managerial capability; and* *(f) any other factor that a procuring agency may deem*

		innovator brand, Technical evaluation committee evaluated and declared the bid of said firm responsive even though our competitor stated that biosimilar study is not available (N/A). As per compulsory parameters of Sole Agents of Foreign Principal at Serial No. VII as well as specifications of Bidding Documents it is mandatory to attach the Biosimilar Study along with the tender documents. Eli Lilly is the Innovator in Human Insulin in rDNA Technology as shown in the link bellow and copy also attached for your review https://americanhistory.si.edu/collections/search/object/nmah_1000967 Similarly, FDA APPROVED DRUG WITH THERAPEUTIC EQUIVALENCE EVALUATIONS 39th EDITION 2019 also confirms this claim. Only HUMULIN 70/30 by Lilly is available in approved drug list and the quoted product of Competitor Company for this tender is not available in the list. Link is given bellow and hard copies attached. https://www.fda.gov/media/71474/download But the compulsory Biosimilar condition is relaxed while evaluating firm S.No.1 in sole agent, item No.4. Please also review your decision regarding firm S.No.1 in sole agent, item No.4. .As you are aware, on 06.07.2019, the Director General Health Services published an Invitation for Prequalification of Drugs/Medicines and Medical Devices for the Financial Year 2019-2020. Prequalification documents were updated. It is submitted that in the corrigendum, Insulin Comp 70/30 Injection is mentioned at serial No.195 but no conditions were attached with this drug, whereas for other products such as the drugs listed	*relevant, not being inconsistent with these rules.* *(4) The procuring agency shall ensure that the prequalification is based on the capacity of the interested parties to satisfactorily perform the services or works.* As evident from above PPR2014 emulates prequalification process as only as only a precondition to decide eligibility to participate in a tender which clearly differentiate bidding process from prequalification hence claim of aggrieved firm insertion of biosimilarity at belated stage is not in line with PPR 2014. Moreover, after prequalification in bidding process, evaluation criteria is mandatory requirement of PPR2014 rule 31 as follows. ***"31. Evaluation criteria. – (1) A procuring agency shall formulate an appropriate evaluation criterion listing all the relevant information against which a bid is to be evaluated and such evaluation criteria shall form an integral part of the bidding documents."*** Underline principle of PPR 2014 rule 25 was followed for bidding documents. Rule 25(j) & Rule 25(f) empowered procuring agency to

		at serial Nos.289, 290, 291, various pre-conditions were prescribed. It is pertinent to note here that on 02.09.2019, Getz Pharma Private Limited was prequalified as a company and its product namely Insuget Injection 70/30 (Insulin Comp 70/30 Injection) was also prequalified. .That on 17.10.2019, the Director General, Health Services uploaded bidding documents in the form of Request For Proposals for various products and to the shock and surprise, the technical specification for Insulin Injection 70/30 (at serial No.37) contains a prerequisite that bioequivalence/biosimilar studies must be attached and the product must be CE/EMA/US-FDA/WHO approved (hereinafter referred to as the 'Impugned Conditions'). It is submitted that the Impugned Conditions were neither mentioned in the original prequalification documents for the Subject Product nor in the corrigendum which was issued in relation to the tender. In fact, the Impugned Conditions were never included in any of the previous tenders for the Subject Product and Getz Pharma has been awarded contracts for the Subject Product in previous tenders issued by the Primary and Secondary Health Care Department. Therefore, the Impugned Conditions are completely illegal. On October 28, 2019 the case was forwarded to UHS and committee was formed headed by Prof. Dr Mr. Javiad Akram. DGHS again issued RFP Phase II on November 9, 2019. The specifications were a little bit changed, (product must be CE/EMA/US-FDA/WHO approved) removed from specifications and compulsory Biosimilar Study of finished form of quoted brand was incorporated both for local manufacturer as well as for sole agent.	incorporate specifications and technical evaluation criteria at bidding stage It is pertinent to write here that every product has its own generic requirements, and technical evaluation criteria in bidding document is laid down by focusing on all factors required by procuring agency in light of PPR 2014. Same was also reiterated in prequalification evaluation report/ notification issued on 3-10-2019 as follows: "*The prequalification of all products is subject to the conformance of the products specification with the specifications advertised/ required later in the bidding document during bidding process."* It is pertinent to mention here that M/s Getz pharma raised its concerns and submitted its representation against evaluation criteria /specification after floating tender on 17-10-2019. To conclude procurement in fair and transparent manner and avoid any discrimination DGHS issued revised bidding document on 26-10-2019 in which Insulin 70/30 was not included. Furthermore, to ensure transparency DGHS to devise/formulate Technical Evaluation Criteria for procurement of Insulin 70/30 after M/s Getz reservation constituted committee of experts under chair of vice chancellor University of Health Sciences

		That under Rule 10 of the Punjab Procurement Rules, 2014 states that the Specifications are to "allow the widest possible competition which shall not favour any single contractor nor put others at a disadvantage". The condition of Biosimilarity Study has been inserted at this belated stage in order to appease our competitor for awarding framework contract of 2 million vials of Human Insulin. Therefore, this condition is violative of, inter-alia, Article 25 of the Constitution, 1973, and Rule 10 of the PPR Rules. That Rule 34 of the PPR Rules defines discriminatory and difficult conditions as "any condition, which discriminates between bidders or which is difficult to meet. Explanation. - In ascertaining the discriminatory or difficult nature of any condition, reference shall be made to the ordinary practices of that trade, manufacturing, construction business or service to which that particular procurement is related". There is no requirement of Biosimilarity Study, as a registration requirement, for a drug to be registered under the Drugs Act, 1976, and they discriminate against everyone except one company. That Rule 4 of the PPR Rules clearly defines the principles of procurement as the following "A procuring agency, while making any procurement, shall ensure that the procurement is made in a fair and transparent manner, the object of procurement brings value for money to the procuring agency and the procurement process is efficient and economical." The Biosimilar Study conditions is also completely illegal and has been inserted at a belated stage. Even otherwise, it is settled law that conditions inserted at belated stages of tender proceedings are illegal and liable to be set	vide notification No. 9090-95/PC to deliberate the bidding criteria for product in question. It is noteworthy that specification and criteria for technical evaluation was finalized in accordance with meeting of minutes of technical expert committee. In said meeting held on 29-10-2019 at University of Health Sciences, three members of committee, experts and learned Professors explicitly questioned the efficacy of insulin manufactured by local manufacture M/s Getz Pharma i.e. Insuget 70/30. DGHS being procuring agency maintained bio similarity condition to ensure quality, safety and efficacy of Insulin to be procured. Moreover, condition of approval of EMA/USA-FDA/JPMHLW/WHO was removed from Specification of Insulin for widest possible competition. The claim of the aggrieved firm regarding introduction of biosimilar studies at belated stage is misleading because same criteria was maintained throughout the bidding process based on prequalification notification 3-10-2019. Hence grievance of the firm regarding introduction of biosimilar studies at belated stage is not acceptable. DGHS followed PPR 2014 in letter and sprit which clearly defines that procurement must be value for money. As per definition of PPR 2014 value for money is defined as

		aside. Furthermore, the entire notion of open competitive bidding is based on the principles of transparency and value for money. These would be completely negated if new conditions are inserted at belated stages of tender proceedings such as after prequalification in relation to the same product. Therefore, the Impugned conditions is violative of, inter-alia, Rule 4 of the PPR Rules.	(ae) "Value for money" means the best returns for each rupee spent in terms of quality, timeliness, reliability, after sales service, up-grade ability, price, source, and the combination of whole-life cost and quality to meet the procuring agency's requirements. Grievance of firm regarding violation of Rule 10 of PPR 2014, is not substantiated by any evidence. In fact, Rule 10 defines that specifications shall be generic and shall not include references, brand name, models etc. for ready reference, Rule 10 is reproduced here under; *"10. Specifications. –(1) A procuring agency shall determine specifications in a manner to allow the widest possible competition which shall not favour any single contractor nor put others at a disadvantage.* *(2) The specifications shall be generic and shall not include references to brand names, model numbers, catalogue numbers or similar other classifications but if the procuring agency is satisfied that the use of, or a reference to, a brand name or a catalogue*

			number is essential to complete an otherwise incomplete specification, such use or reference shall be qualified with the words "or equivalent". DGHS being a procuring agency laid down evaluation criteria to procure quality medicines. The specifications advertised by the DGHS were generic and did not included any specific reference, brand name, model catalogue or similar other barred classifications and complied fully as per PPR-2014. Hence, grievance of the firm regarding violation of rule 10 is not acceptable. As far as grievance of the firm regarding Rule 34 of PPR 2014 is concerned, bio similarity study is neither a condition which is difficult to meet nor a requirement which is against the ordinary practices of the trade etc. In addition, Bio similarity is commonly used criteria for others biotech products excluding vaccines and immunogenic products and same was vigorously exercised in the procurement of biotech products. For instance, bidding document issued by DOW University of Health Sciences Karachi, N.I.T No.

			DUHS/DP/2016/11 dated 19th September 2016 have also biosimilar studies of finished product as a knock down parameter for insulin in technical specification. Similarly, standard bidding document issued by Medicine Coordination Cell (MCC) issued by Govt. of KPK Health Department, Director General Health Services on February 2018 bio similarity was also laid down as technical evaluation criteria. In addition, Honorable High court Lahore in W.P. No. 10045 of 2016 also upheld the Bio similarity as a quality standard for biologics/Biotech products. In fact Biosimilar studies must be implemented to ensure efficacy of medicines because these are directly related to human life. WHO guidelines on evaluation similar bio therapeutic products (SBP) defines ''Bio similar biological drug means similar bio therapeutic product which is similar in terms of quality, safety and efficacy to an already reference by therapeutic product" Same document further elaborates that;

			"A SBP is intended to be similar to a licensed bio therapeutic products for which there is a substantial evidence of safety and efficacy." Same guidelines further stated that "The main clinical study should use the final formulation derived from the final process material of similar bio therapeutic product." Hence grievance of the firm regarding violation of 34 is not acceptable. Grievance of the firm regarding Rule 4 of PPR 2014 is also not acceptable because to conclude the procurement in fair and transparent manner DGHS constituted a special committee of experts vide notification No. 9090-95/PC to finalize the specifications and bidding criteria for the product in question. In addition, no principle of procurement is violated in the subject procurement process and fully complied PPR 2014 rule 4. as per PPR 2014 Rule 2 definition of value for money as fallows. (ae) „ „value for money" means the best returns for each rupee spent in terms of quality, timeliness,

			reliability, after sales service, up-grade ability, price, source, and the combination of whole-life cost and quality to meet the procuring agency's requirements. Moreover, the claim of the aggrieved firm regarding introduction of biosimilar studies at belated stage is misleading because same criteria was maintained throughout the bidding process based on prequalification notification 3-10-2019. Hence grievance of the firm regarding introduction of biosimilar studies at belated stage is not acceptable. Grievance Redressal Committee has decided the matter on merit as per direction of the honorable Lahore high court Lahore in accordance with rules and regulations. As it is a policy matter and cannot be considered for firm's own interest of business and exercised throughout the procurement process, hence Grievance of the firm is rejected and upheld the decision of Technical Evaluation Committee.