RESULT OF GRIEVANCE COMMITTEE MEETING HELD ON 20-02-2018 TO ADDRESS THE GRIEVANCES RECEIVED IN BULK PURCHASE OF MEDICINES FOR THE ESTABLISHMENT OF HEPATITIS CLINICS AND GI DEPARTMENTS IN ALL TERTIARY CARE HOSPITAL IN PUNJAB.

A meeting to address the Grievances received as mentioned above was held on 20-02-2018 in the committee room of Lahore General Hospital Lahore.
After hearing the aggrieved firms & having the elucidative session, the grievance committee decided as under:

1. **Grievance submitted by:** **M/s Roche Pharma**
   Item's Name: **Pegylated Interferon Alpha 2A**
   T.E No. **06**

Grievance	Decision of Grievance Committee
M/s Roche Pharma has submitted Grievance vide Diary letter No.242 Dated 16-02-2018. The company claims that there are no Biosimilars, as per WHO guidelines on evaluation of similar Biotherapeutic products (SBPs), for various Inj.PEGYLATED INTERFERON ALPHA 2 A available in Pakistan. Hence company request that Biosimilarity evaluation for any product quoted in the Tender Enquiry in comparision to the Reference Biotherapeutic Product (RBP), be reconsidered keeping in view the following criteria laid down in Guidelines on evaluation of Similar Biotherapeutic Product (SBP), 2009, as part of the WHO Technical Series 977, 2013 and reference found in DRAP Act 2012. i. There should be a head-to-head comparison of any product that claims to be a biosimilar/similar biotheraputic product with the reference biotheraputic product in the same clinical study. ii. The reference biotherapeutic product is always an originator product. iii. Biosimilarity means, the similar biotherapeutic product is highly similar to the reference biotherapeutic product in terms of quality, safty and efficacy and there are no meaningfully differences as supported by head-to-head clinical trial. iv. The preferred clinical trial design is equilance to demonstrate Biosimilarity of a proposed Biological in comparison to the originator molecule. v. The head-to-head trial should be adequately powered. vi. The head-to-head clinical trial to demonstrate biosimilarity must be a prospective study. vii. The population of the head-to-head clinical trial demonstrate Biosimilarity should be sensitive enough to detect the differnces between a proposed similar Biotherpeutic product and the reference Biotherapeutic product. viii. The head-to-head clinical trial should be double-blind or at least observer blind. It has been addressed by Honourable Lahore High Court in its decision of W.P.No.10045 of 2016 M/s Alfalah Medicos (authorized distributor of Getz Pharma) and another Versus Government of Punjab and others (Copy of the decision attached). The said Honorable Court justified the Government of Punjab's decision to reject Getz Pharma's bid on the basis that its drug was non-compliant with the DRAP Act and relevant WHO Guidelines.	After hearing the aggrieved firm, elaborative discussion and pondering into fine detail of the matter the committee develops the consensus that the Grievance submitted by the M/s Roche Pharma has many strong reasons / justifications to be considered & they have well established and adequate internationally published studies in Hepatitis B & D viruses. **Henceforth the committee unanimously agrees with view point of M/s Roche & accept their grievance.**

2. **Grievance submitted by:** **M/s Getz Pharma**
   Item's Name: **Pegylated Interferon Alpha 2A**
   T.E No. **06**

Grievance	Decision of Grievance Committee
Getz Pharma has submitted grievance vide Diary letter No.3575 Dated 14-02-2018. Getz Pharma has recently acquired the distinction of being the "World Health Organization (WHO) accredited the first-ever Pakistani company" an outstanding & unrivalled achievement for Pakistan and a matter of great pride for the country. The WHO Prequalification means the drug can now be sold to world	After detail discussion and hearing the aggrieved firm, the Grievance committee is of the opinion that the Inj. Unipeg, Manufactured by M/s Getz Pharma has no clinically published evidence regarding the treatment of Hepatitis B& D. In this project Pegylated Interferon is being procured for the treatment of Hepatitis B. **Hence forth the committee unanimously turns down the grievance submitted by M/s Getz Pharma and the product still**

bodies like the Unicef and will lead to approval by the US, the EU and other developed Countries for sale. As per attached order of Honorable Supreme Court and High Court of Sindh, Unipeg is equally Safe, Potent and efficacious in accordance with other available Brands. Civil Petitions No. 16 and 17 of 2016	**stands rejected.**

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