MINUTES OF GRIEVANCES MEETING

MAYO HOSPITAL LAHORE

Venue: Department of Neurology, Mayo Hospital Lahore
Date & Time: 10-08-2023

Participants:

1.	**Prof. Dr. Ahsan Numan** Head of Neurology Department Mayo Hospital Lahore	**Chairman**
2.	**Prof. Dr. Nasir Chaudhary** Head of Ophthalmology Department Unit-II Mayo Hospital Lahore	**Member**
3.	**Dr. Sohail Arshad** *Addl. Directors Stores Mayo Hospital Lahore*	**Member**
4.	**Mr. Azeem Butt** *Deputy Drugs Controller Mayo Hospital Lahore*	**Member**
5.	**Mr. Muhammad Jawad Bhatti** *Deputy Drugs Controller Mayo Hospital Lahore*	**Member**

Proceedings:

Meeting started with the recitation from the Holy Quran. The Chairman, Grievances Committee Mayo Hospital Lahore welcomed all the participants.

ITEM NO. 01: **GRIEVANCE SUBMITTED BY M/S NOVARTIS PHARMA (TENDER CODE: CML-01)**

GRIEVANCE DETAIL: The firm submitted grievance while claiming that Tasigna is a Patented product of Novartis Pharma Pakistan Limited. Five patents ware registered for this product with Nos. 142072 142073, 142172, 143645, 143724 with the latest patent expining on 17 Nov 2029 Firm claims to have attached letters addressed to IPO and DRAP with grievance as ready reference that was meant to halt the registration of further nilotinib generics. Hence based on the following points any generic participating in the bidding procedure should be disqualified and be devoid of any marks given for previous experience.

Grievance Against Pharmasol

The firm claimed that previously, Pharmasol offered its product for sale, Novartis initiated its legal proceedings to challenge the infringement of its patents No 142072 142073. The same facts were produced in the health

Department Government of the Punjab which were accepted for which the evidence is as follows;

1) Pharmasol Pvt Limited registered Nilotinib in DRAP in 2019 whereas Patent No. 142072 and 142073 of Cap Tasigna were intact till 5th July 2022.
2) Subsequently a suit was filed by Novartis pharma against Pharmasol Pvt. Limited before the Intellectual Property Tribunal Punjab, Lahore. Consequently, the stay orders for the grant of perpetual injunction to restrain the defendant (Pharmasol) from committing any infringement and/or counterfeiting and/or imitation of Plaintiff's (Novartis Pharma) rights in its patent No 142072 and No 142073 and for damages etc. were issued dated 19 December 2019.
3) Pharmasol were restrained from Manufacturing, importing, exporting, marketing, formulating, launching, offering for sale and selling the disputed drug Nilotinib alone or in combination with any other active ingredients or salt from under any name.
4) In reply to this suit defendant (Pharmasol) submitted undertaking before IPT Punjab, Lahore on their letter head Dated 5th September 2023 that they shall keep commercialization of Nilotinib on hold till the expiration of relevant patent or injunction whichever comes first.
5) In the light of above undertaking of defendant (Pharmasol), IPT Punjab Lahore Dated 23rd September 2023 ordered that the suit of the Plainsff (Novartis Pharma) is decreed to the extent of permanent injunction
6) Furthermore as per minutes of 24 meeting of provincial (Punjab) cabinet Dated 30 January 2020 having agenda for continuation of Punjab CML point no 14. 12 (2) which clearly mentions that cabinet constituted a negotiation committee to negotiate fresh MoU with M/S Novatis for next FY i.e. 1st July 2020 till the patency of Tasigna i.e. 2022. This minute of meeting concluded that the mentioned patents of Tasigna were intact till 2022.
7) In addition to that as per minutes of provincial (Punjab) cabinet meeting held on 11th March 2021 having agenda for proposal of negotiations committee for approval and further direction on Punjab CML Project (SHC & ME), point no. 25. 12 clearly mentioned that M/S Pharmasol Pvt Limited did not offer Nilotinib to SHC & ME department Lahore, Punjab due to Patent of Tasigna

8) Subsequently Pharmasol Pvt Limited also wrote a letter Dated 08th September 2022 to Secretary, SHC & ME department. Lahore with the subject of unavailability of Nilotinib in market which stated that due to IPQC patent protection rules they have to wait for manufacturing and marketing of their Nilotinib until patent of Tasigna expires and only after that they will start its manufacturing and marketing Information about this letter can also be verified from SHC & ME department Lahore Punjab by Mayo Hospital Lahore.

Keeping in view the above facts we are aggrieved of the decision made in the Technical Evaluation Committee regarding the following;

1. Passing of Product Nilotinib quoted by Pharmasol as Patents of Tasigna are valid till 2029. And we are going into litigation for the infringement of further patents. Same has been mentioned in letters addressed to DRAP and IPO.
2. Furthermore, the mentioned firm cannot also claim the product experience of 4 years and 15 Marks as they were legally bound and themselves accepted to not manufacture the products till expiry of patents.
3. Also the claim of the company regarding its API of Nilotinib should also be reevaluated from National Drug Code Directory. Which must be FDA/EMA/TGA certified as per the compulsory criteria of evaluation. Hence the firm Pharmasol should be disqualified for this product.

Grievance Against Himmel

The firm stated that Tasigna is Patented product of Novartis Pharma Pakistan Limited. Five patents are registered for this product with Nos. 142072, 142073. 142172, 143645, 143724 with the latest patent expiring on 17 Nov 2029. Furthermore, the firm has claimed to attach letters addressed to IPO and DRAP for ready reference, to halt the registration of further nilotinib generics. Hence, based on the following points any generic participating in the bidding procedure should be disqualified and be devoid of any marks given for previous experience. The firm added following points:

1. Previously, as Himmel offered its product for sale, Novartis has initiated its legal proceedings to challenge the infringement of our three above mentioned valid patents in Intellectual Property Tribunal Punjab, Lahore.
2. The API of Niotinib of Himmel should be reevaluated for its FDA/EMA/TGA certification as to our knowledge the API of Nilotinib or finished good is not FDA/EMA/TGA certified as per National Directory Code which is compulsory criteria.

Keeping in view the above facts the firm stated that it is aggrieved of the decision made in the Technical Evaluation Committee regarding the Passing of Product Nilotinib quoted by Himmel as Patents of Tasigna are valid till 2029. And Himmel Pharma also does not qualify the compulsory criteria. Hence, the firm Himmel Pharma for this product should be disqualified.

Decision:

Mr. Umer Asghar, Key Accounts Manager & Mr. Mehmood, Key Accounts Manager of M/S Novartis pleaded the grievance before the grievances committee. Mr. Zafar Zaidi, Sales Manager & Syed Tariq Ajmal, Institutional Manager of Pharmasol defended the grievance. Novartis Pharma presented the above-mentioned grievance pertaining to Patent. The defendant contended that the matter does not pertain to bidding document evaluation criteria. The petitioner claimed that API source of Pharmasol is not FDA approved as the defendant has quoted API source (Nilotinib) of Shandong Lixin Pharmaceutical Co., Ltd. that is not available on FDA National Drug Code Directory. The same was checked online . The defendant then provided Certificate of Suitability issued by European Directorate for the Quality of Medicines and HealthCare (EDQM). The committee observed that Companies making applications to the Agency can apply to the EDQM for a certificate of suitability to confirm compliance with European Pharmacopoeia monographs for their medicines' components. These certificates cover their chemical purity, microbiological quality and/or steps necessary to reduce the risk of transmission of spongiform encephalopathies (TSE). The certificates can form part of the application dossiers submitted to the Agency as part of marketing-authorization applications. The defendant failed to provide EMA authorization. The petitioner claimed that the defendant did not commercialize its brand till July 2022 and 15 marks attributed by TEC in Section 2 shall be reconsidered. The defendant admitted that the firm did not

have commercial experience before July 2022- thus proved that the firm has less than 4 years experience. **The committee decided to reduce points to 7 in Section 2 of Part-B for T.E. Nilotinib. The quoted item T.E: Nilotinib quoted by M/S Pharmasol stands non-responsive in T.E: Nilotinib due to failure in Section 12 of Part-A and Part-B due to less marks 48 in Part-B.**

The committee also discussed the grievance against M/S Himmel Pharmaceuticals. Mr. Saifullah Niazi, Director & Mr. Imtiaz Malik, Business Unit Head defended the case on behalf of M/S Himmel Pharmaceuticals. The defendant contended that the said matter does not pertain to bidding document & evaluation criteria. The petitioner claimed that the defendant API source is not FDA approved. The defendant claimed that it's API source is Suzhou Lixin Pharmaceutical Co., Ltd. which is available on FDA National Directory Code. The same was verified online. **The committee decided to turn down the grievance against M/S Himmel Pharmaceutical.**

ITEM NO. 02: **GRIEVANCE SUBMITTED BY M/S HIMMEL PHARMACEUTICALS (TENDER CODE: CML-01)**

GRIEVANCE DETAIL: The firm submitted grievance in response to the announcement of the technical evaluation report regarding the purchase of medicines for the financial year 2023-24 (Tender code CML-01), where the firm has quoted item Cap Nilonix (Nilotinib) 200mg. Himmel Pharmaceuticals (Pvt.) Ltd submitted its request for grievance meeting that is as follows:

The firm stated that it has been declared responsive by obtaining the qualifying marks i.e. 65% in Part-B of tender documents but it has reservations regarding the distribution of marks given by the technical committee. The firm submitted following response to each objection:

Sr. No.	Parameters	Marks given by technical committee	Documents Submitted	Marks claimed
1	Past performance of the bidder	10	8 & Above	10
2	Product experience	07	2-3 years	10
3	Quality certification of manufacturer	10	USFDA/ISO equivalent certification	10

4	Batch history last year	Not applicable	Annual production history	Not applicable
5	Batch Quality on stamp paper	05	No batch failed during the last three years	05
6	Financial Capacity of the bidder	10	1000 million or above	20
7	Institutional performance at Mayo	10	Supplied quoted items as per order within the stipulated delivery period	10
	Total Marks Given by Technical Committee	**52**	**Marks claimed**	65

The firm added that total marks given by technical committee are 52 out of which it should have been awarded minimum 65 marks that is more than 90% as per the submitted documents. So it is requested to please accept request for grievance.

Grievance against Pharmasol

The firm submitted grievance against the acceptance of Cap Nitonib 200mg by M/S Pharmasol in Mayo Hospital Lahore tender Code CML-01

Part-A Compulsory Parameters of the tender:

7. (Product Experience: Product having less than one-year experience shall be ineligible.)

The firm claimed that the quoted item from Pharmasol has less than one year of experience, hence in accordance with the compulsory parameters of the bidding documents, the product should be deemed ineligible.

12. (Credibility and Quality Certification of API or finished Product: Valid quality certification by USFDA/EMA/TGA.)

The firm claimed that according to its research, the API source utilized to make Pharmasol (Nitonib) is not US FDA/EMA/TGA authorized. If the USFDA, EMA, or TGA approve it, we request the grievance committee to match FDA approval with FTA certificate.

Part-B Technical Evaluation Parameters: Marking Criteria

2. (Product Experience (National / International: Sale supply of quoted item.) The claim required Commercial invoices for chain pharmacies and purchase orders of any Govt/ semi Govt institutions).

The firm claimed that as per its reliable sources M/S Pharmasol has imported commercial API consignment of nilotinib for the first time after its registration in Feb 2023. Hence, they can't claim an experience of being in the market for last 04 years. Which means that if they have submitted invoices of retail pharmacies / hospitals of last 04 years must be fake. Moreover Punjab & KP Government has been working with Novartis on this product as part of CML project since last few years & Sindh Government working with Himmel Pharmaceuticals (Pvt.) ltd for Nilotinib since last one year, which means that the quoted item of Pharmasol have no experience in institutional / market sales at all. The firm added that it has reservations regarding the documents attached by the Pharmasol for the product experience that are not authentic & must be fake. The firm requested the grievance committee to check and verify these documents.

4. (Batch History Last year: Annual production batch history).

The firm reiterated that that M/S Pharmasol has imported first commercial consignment of API in Feb 2023 & with no supplies in any major hospital all over the Pakistan so how can they manufacture 10 batches in a short span of 04 months, which means that the documents of batches which they have submitted must be fake. The firm requested the committee to kindle verify these documents as well.

Decision:

Mr. Saifullah Niazi, Director & Mr. Imtiaz Malik, Business Unit Head pleaded the case of firm before the grievances committee. The firm claimed that the TEC has awarded less marks in Section 2 of Part-B i.e. 7. The firm claimed that it has more than 2 years International experience and showed Certificate of Marketing Authorization having Authorization No. 341-389-410 bearing date of Authorization 26th Sep 2019 in favor of M/S Beacon Pharmaceuticals for Nilonix 200 issued by Government of People's Republic of Bangladesh. **The committee awarded 10 marks in Section 2 of Part-B.** The firm further claimed 20 marks in Section 6 of Part-B as its FBR statement for the year 2021-22 shows Net Revenue at Rs. 1,006,121,611. **The committee observed that the**

firm is already responsive in Part-B having 52 marks, accepted the grievance and awarded 20 marks in section 6 of Part-B. Resultantly, the score increased to 65 in Part-B for T.E: Nilotinib.

The committee also discussed the grievance against M/S Pharmasol. Mr. Zafar Zaidi, Sales Manager & Syed Tariq Ajmal, Institutional Manager of Pharmasol defended the grievance. The petitioner claimed that the defendant API source is not FDA approved and also challenged the score in Section 2 of Part-B, **for which the decision has already been taken in Agenda Item No. 1.** The petitioner further claimed that the TEC has awarded 3 marks in Section 4 but the defendant has less than 10 batches. The committee observed that the firm has manufactured only one Batch in the last year and **deducted 3 marks from Section 4. Resultantly, Pharmasol bid stands disqualified in T.E: Nilotinib due to failure in Section 12 of Part-A and Part-B due to less marks 45 in Part-B.**

ITEM NO. 03: **GRIEVANCE SUBMITTED BY M/S A.J. MIRZA (TENDER CODE: CML-01)**

GRIEVANCE DETAIL: The firm submitted grievance with reference to the Technical evaluation report of Purchase of Cancer Medicines (Imatinib) for the financial year 2023-2024 issued on 31 July 2023. The firm stated following grievances;

Grievance against Pharmasol

1. Pharmasol Pvt Ltd have been given 15 marks in Clause # 2 "Product experience" of Part B (Technical evaluation Parameters). Registration date of their brand Glynib 100mg is 11 Oct 2019 which is not equivalent to 4 years at the time of submission of Bid. Experience of their product fall under 2-3 years (sub clause ii). Please review.
2. Pharmasol Pvt Ltd have been given 05 marks in Clause # 4 "Batch History Last Year" of Part B (Technical evaluation Parameters). Pharmasol have claimed manufacturing of 16-20 batches. As provided document against the said claim is inhouse and can be fabricated according to need. You are requested to verify their claim from Commercial Invoices of claimed batches, batch manufacturing record as well as API Import trail of claimed batches.

Grievance against Crown Pharma

The firm raised following grievances;

1. Crown Pharmaceutical Pvt Ltd is authorized distributor of Rotex Pharma for the quoted brand Gvec 100mg for this esteemed institute. The firm claimed that in a recent inspection of Drug Regulatory Authority of Pakistan at the site of manufacturing of M/S Rotex Pharma, they have found many flaws and reported observation leading to issuance of show cause against the firm and shut down of manufacturing facility. Inspection team reported major deficiencies in product quality, risk of contamination, qualification of equipment and facility etc. GMP report of M/S Rotex Pharma also shows NON- COMPLAINT on DRAP website.
2. The firm added that Crown Pharma Pvt Ltd have been given 10 marks in Clause # 4 "Batch History Last Year" of Part B (Technical evaluation Parameters). Crown Pharmaceuticals Pvt Ltd have claimed manufacturing of more than 20 batches. As provided document against the said claim is in-house and can be fabricated according to need. The firm requested to verify their claim from Commercial Invoices of claimed batches, batch manufacturing record as well as API import trail of claimed batches.

   The firm concluded that all above parameters affecting GMP & quality of medicine, as this medicine is for cancer patient and their well-being is the priority. The firm requested to review accordingly.

Decision:

Mr. Javed Islam, General Manager pleaded the case before the grievances committee. Mr. Zafar Zaidi, Sales Manager & Syed Tariq Ajmal, Institutional Manager of Pharmasol. The petitioner claimed that the defendant API source is not FDA approved as its not available on FDA National Directory Code The committee observed that API source of Guang'an Kingday Pharma & Chem Co., Ltd.is not available on FDA National Directory Code and **decided to declare firm non-responsive in Section 12 of Part-A for T.E. Imatinib.** The petitioner further claimed that Pharmasol Quoted product was registered on 11th Oct 2019 and the TEC has awarded 15 marks in Section 2 of Part-B. **The committee observed that the product experience of T.E. Imatinib is less than 4 years and reduced marks to 10 in section 2 of Part-B.** The petitioner further claimed that the TEC has awarded 5 marks in Section 4 of Part-B but the firm has manufactured less number of batches. The committee observed that the firm has produced 11 batches in the last year and **deduced 02 marks in**

Section 4 of Part-B. The Pharmasol Bid stands disqualified due to failure in Section 12 of Part-A and due to less marks in Part-B 51 out of 80.

The committee also discussed the grievance against M/S Crown Pharmaceuticals. Mr. Arslan Haider, Director Sales and Rana Hassaam, Assistant Manager defended the grievance on behalf of M/S Crown Pharmaceuticals. The petitioner claimed that the manufacturer is GMP non-compliant on DRAP website. The defendant claimed that the DRAP conducted inspection for the purpose of WHO benchmarking and was not for GMP renewal. The petitioner further claimed that the firm has manufactured less than 16 batches in the last year. The committee observed that the firm has enclosed certificate of more than 20 batches **The committee decided to turn down the grievance against M/S Crown Pharma.**

ITEM NO. 04: **GRIEVANCE SUBMITTED BY M/S CROWN PHARMACEUTICALS (TENDER CODE: CML-01)**

GRIEVANCE DETAIL: The firm submitted grievance with Reference to the technical evaluation report for CML-01 2023-24, The firm stated that it has obtained 56 marks out of 70, according to which Crown Pharmaceuticals Pvt Ltd, has scored more than the required marks in part B. However, online verification link of quality certification of API was not provided on demand, because the manufacturer ROOTEX PHARMA having factory and head office in the premises of Islamabad was closed for five days due to public holidays. Government announced two holidays for 9th & 10th of Moharum Ul Haram i.e 28th July 2023 (Friday) to 30th July 2023 (Sunday). Afterwards two public holidays were announced locally in Islamabad from 31st July 2023 (Monday) to 1st August 2023 (Tuesday) for the security of higher Chinese delegation. Due to above mentioned publicly announced local holidays, the firm claimed that it was not able to provide online links of quality certification of API.

The firm claims that it has now obtained the required online links from the manufacturer and is therefore providing the links along with the screen shots, and other documents of the said API. The firm requested to consider the bellow mentioned links

1. https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm
2. http://extranet.edqm.eu/4DLink1/4DCGI/Query_CEP

3. https://www.natcopharma.co.in/our-business/apis/

The firm requested to accept its grievance petition as they have already mentioned above the cause of delay in providing the links.

Decision:

Mr. Arslan Haider, Director Sales and Rana Hassaam, Assistant Manager pleaded the case of firm before the grievances committee. The firm presented the grievance and claimed that its product is FDA & EMA approved. The firm claimed to have API source from M/S Natco Pharma and produced some unattested poor copies of Good Declaration GD-1 depicting Natco Pharma Limited as its source. The committee observed that the firm has attached documents of Khandewal Laboratories Pvt. Ltd. India in its technical bid claiming its source of API. The committee observed that it tantamounts to violation of subsection (2) of Section 33 of PPRA Rules 2014 where it speaks that:

> ***"The procuring agency may, if necessary after the opening of the bids, seek and accept such clarifications of the bid as do not change the substance of the bid".***

The firm also provided unattested copies of Airway Bill, Commercial Invoices from Natco Pharma. The committee observed lot of disparities in newly submitted documents i.e the font size of Natco Pharma mentioned on Good Declaration GD-1 certificates was not congruent with rest of document. The committee suspected that submitted poorly readable GD bearing Serial No. 2395 was fabricated copy of GD Serial No. 2395 attached in Bid. The committee observed that the Batch Nos. mentioned on both copies is 20220705/ 20220706 having manufacturing date 07.2022 while source on both copies is different. **It raised concerns how two different firms manufactured same batches of same API on same date.** Disparities were also noted in the GD No. 82013 attached with grievance that also contained same Batch nos of API but bearing different manufacturing date i.e. 12/2022, however the expiry date was same i.e. 06/2027. The information under section 58 was also same in GDs from different sources. Furthermore, the batches mentioned on provided commercial invoices were different i.e. 07052022 & 07062022 on Invoice No. NT219222 dated June 2022 & 78463857 & 75315787 on Invoice No. NT021892 dated Jan 2022. It is added that the HS

code No. 90200294 mentioned on both Commercial Invoices was invalid and different from HS Code 2933.4990 mentioned on Airway Bill. The firm also provided fabricated/ forged Airway Bill bearing AWB No. 265-89034-035689 through Gulf Air that turned out to be invalid on verification from Gulf Air official website. The Invoice number was also different from Invoice numbers mentioned commercial invoices. **The committee decided to uphold the decision of Technical Evaluation Committee. The committee also requested the procuring agency to note the discrepancies, contact the Principal and initiate suitable legal action provided under PPRA Rules 2014.**

The meeting ended with vote of thanks to and by the Chair.

Mr. Muhammad Jawad Bhatti
Deputy Drugs Controller
Mayo Hospital Lahore

Mr. Azeem Butt
Deputy Drugs Controller
Mayo Hospital Lahore

Dr. Sohail Arshad
Addl. Director Stores
Mayo Hospital Lahore

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