

(NON-CONFIDENTIAL)



**Government of Pakistan
National Tariff Commission**

Report

On

**Preliminary Determination in Anti-Dumping Investigation against
Alleged Dumping of Pegylated Interferon Alpha-2A into Pakistan
Originating in and / or Exported From Switzerland**

**A.D.C No. 29/2012/NTC/PIA
July 23, 2013**

The National Tariff Commission (hereinafter referred to as the “Commission”) having regard to the Anti-Dumping Duties Ordinance, 2000 (LXV of 2000) (hereinafter referred to as the “Ordinance”) and the Anti-Dumping Duties Rules, 2001 (hereinafter referred to as the “Rules”) relating to investigation and determination of dumping of goods into the Islamic Republic of Pakistan (hereinafter referred to as “Pakistan”), material injury to the domestic industry caused by such imports, and imposition of anti-dumping duties to offset the impact of such injurious dumping, and to ensure fair competition thereof and to the Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994 (hereinafter referred to as the “Agreement on Anti-dumping”).

2. The Commission is conducting this investigation on imports of Pegylated Interferon Alpha-2a, into Pakistan originating in and/or exported from Switzerland. The Commission has made preliminary determination in this investigation under Section 37 of the Ordinance. This report on preliminary determination has been issued in accordance with Article 12.2 of the Agreement on Antidumping.

3. In terms of Section 37 of the Ordinance, the Commission shall make a preliminary determination of dumping and injury, if any, not earlier than sixty days and not later than one hundred and eighty days, after initiation of an investigation. Such preliminary determination shall be based on the information available to the Commission at that time. This investigation was initiated on December 14, 2012. The Commission was required to make preliminary determination in this investigation within 180 days from the date of initiation of investigation i.e. by June 13, 2013. However, the composition of the Commission remained incomplete during the period from May 24, 2013 to July 8, 2013 (due to transfer/posting of one of its Member) and the Commission was not properly constituted during this period in the light of decision of Honorable Supreme Court of Pakistan dated Oct. 29, 2009 in Civil Petitions Nos. 1608, 1654, 1686-1687, 1706-1708/2009. Therefore, the Commission has adjusted the timeline for making preliminary determination by twenty-one days (during which the composition of the Commission was incomplete) and now the 180 days period for making preliminary determination would be till July 30, 2013. The preliminary determination is based on the information available to the Commission at this time.

A. **PROCEDURE**

4. The procedure set out below has been followed in this investigation.

5. **Receipt of Application**

5.1 On October 15, 2012 the Commission received a written application under Section 20 of the Ordinance from M/s Getz Pharma (Private) Limited, Karachi (hereinafter referred to as the “Applicant”). The Applicant alleged that Pegylated Interferon Alpha-2a originating in and/or exported from the Switzerland is being dumped into Pakistan, which has caused and is causing material injury to the domestic industry producing the Pegylated Interferon Alpha-2a.

5.2 The Commission started proceedings in this case and informed the Embassy of Switzerland in Islamabad through a note verbale dated October 19, 2012 of the receipt of application as required in Section 21 of the Ordinance.

6. Evaluation and Examination of the Application

The Commission examined the application filed by the Applicant (M/s Getz Pharma). The Commission's analysis showed that the application met requirements of Section 20 of the Ordinance as it contained sufficient evidence of dumping of Pegylated Interferon Alpha-2a into Pakistan from the Switzerland and material injury to the domestic industry caused therefrom. Requirements of Rule 3 of the Rules, which relate to the submission of information prescribed therein were also found to have been met.

7. The Domestic Industry

7.1 Section 2(d) of the Ordinance defines domestic industry as:

"domestic industry" means the domestic producers as a whole of a domestic like product or those of them whose collective output of that product constitutes a major proportion of the total domestic production of that product, except that when any such domestic producers are related to the exporters or importers, or are themselves importers of the allegedly dumped investigated product in such a case "domestic industry" shall mean the rest of the domestic producers".

7.2 As per information gathered by the Commission in this investigation, the domestic Pegylated Interferon Alpha-2a manufacturing industry comprises of the following units:

- i. M/s Getz Pharma (Private) Limited, Karachi.
- ii. M/s BF Biosciences, Lahore (Subsidiary of M/s Ferozsons Laboratories Private Limited).

7.3 M/s Getz Pharma (Private) Limited, Karachi (M/s Getz Pharma) started commercial production of Interferon Alpha 2a in July 2010. The present production capacity of M/s Getz Pharma is 425,000 vials per annum, against actual production of 105,196 vials per annum.

7.4 The installed production capacity of BF Boisciences, other unit in the domestic industry, of Pegylated Interferon Alpha 2a is 600,000 vials per annum, while actual production during 2011-12 was 120,539 vials per annum.

8. Standing of the Application

8.1 In terms of Section 24(1) of the Ordinance,

".... an application shall be considered to have been made by or on behalf of the domestic industry only if it is supported by those domestic producers whose collective output constitutes more than fifty percent of the total production of a domestic like product produced by that portion of the domestic industry expressing either support for or opposition to the application."

Furthermore, Section 24(2) of the Ordinance provides that:

“..... no investigation shall be initiated when domestic producers expressly supporting an application account for less than twenty five percent of the total production of the domestic like product produced by the domestic industry.”

8.2 As stated in paragraph 7 supra the domestic industry manufacturing Pegylated Interferon Alpha-2a comprises of two units. The Commission forwarded the notice of initiation to the other producer i.e. BF Biosciences, Lahore (hereinafter BFB). The BFB in response, requested to register it as an interested party in this investigation and showed its support for the application filed by M/s Getz Pharma with the Commission for anti-dumping investigation against dumping of Pegylated Interferon Alpha 2a from Switzerland.

8.3 As per the information supplied in the application and obtained from other sources, the Applicant produced 46.60 percent of the total domestic production of Pegylated Interferon Alpha-2a during the year 2011-12. Details of the production of Pegylated Interferon Alpha-2a by the domestic industry are as follows:

Table-I
Unit-wise Production of Pegylated Interferon Alpha 2a during FY 2011-12

Domestic Producers	Vials produced	Status
M/s Getz Pharma (pvt) Ltd., Karachi	46.60%	The Applicant
M/s BF Biosciences, Lahore (a subsidiary of Ferozsons Laboratories Limited).	53.40%	Supporting the application

8.5 The above table shows that the Applicant accounted for 46.60 percent of the total production of Pegylated Interferon Alpha-2a during FY 2011-12 and the other unit supporting the application i.e. M/s BFB produced around 53.40 percent. On the basis of this information and analysis, the Commission has determined that the application was made on behalf of domestic industry, as it is supported by those domestic producers whose collective output constitutes 100 percent of the total production of the domestic like product produced by that portion of the domestic industry expressing support for the application. Thus the application fulfils the requirements of Section 24 of the Ordinance.

9. Applicant' Views

The Applicant, *inter alia*, raised the following issues in the application regarding alleged dumping of Pegylated Interferon Alpha-2a and material injury to the domestic industry caused therefrom:

- i. Pegylated Interferon Alpha-2a imported from Switzerland into Pakistan is patented Pegylated Interferon Alpha-2a and the domestic industry in Pakistan is producing bio-similar Pegylated Interferon Alpha-2a, which are like products;
- ii. Exporter/producer from Switzerland is exporting Pegylated Interferon Alpha-2a to Pakistan at dumped prices; and
- iii. Exports of Pegylated Interferon Alpha-2a by the exporter/producer from Switzerland to Pakistan at dumped prices has caused and is causing

material injury to the domestic industry producing Pegylated Interferon Alpha-2a mainly through:

- increase in volume of alleged dumped imports during the POI relative to sales by domestic industry;
- negative effects on inventories;
- price suppression;
- price depression;
- negative effects on market share;
- increase in losses;
- negative effects on return on investment; and
- negative effects on cash flows;

10. Exporter/Foreign Producer of Interferon Alpha-2a

The Applicant has identified only one exporter/producer i.e. Hoffmann-La Roche, involved in dumping of Pegylated Interferon Alpha-2a from Switzerland.

11. Initiation of Investigation

11.1 The Commission upon examination the accuracy and adequacy of the evidence provided in application established that there is sufficient evidence of alleged dumping of Pegylated Interferon Alpha-2a into Pakistan and consequent material injury to the domestic industry to justify initiation of an investigation. Consequently, the Commission issued a Notice of Initiation in accordance with Section 27 of the Ordinance, which was published in the Official Gazette¹ of Pakistan and in two widely circulated national newspapers² (one in English language and one in Urdu Language) on December 14, 2012. Investigation concerning alleged dumped imports of Pegylated Interferon Alpha-2a into Pakistan {classified under PCT³ Nos. 3002.2090 contained in the First Schedule of Customs Act, 1969 (IV of 1969)} originating in and/or exported from Switzerland was thus initiated on December 14, 2012.

11.2 The Commission notified Embassy of Switzerland in Islamabad of initiation of investigation (by sending a copy of the notice of initiation) on December 14, 2012. Copies of the notice of initiation were also sent to known Pakistani importer, Pakistani producers of Pegylated Interferon Alpha-2a and the Applicant on December 14, 2012 in accordance with the requirements of Section 27 of the Ordinance.

12. Investigated Product, Like Product and Domestic Like Product

12.1 Section 2 of the Ordinance defines the “investigated product”, the “like product”, and the “domestic like product” as follows:

i. Investigated Product:

“a product, which is subject to an antidumping investigation as described in the notice of initiation of the investigation”.

¹ The official Gazette of Pakistan (Extraordinary) dated December 14, 2012.

² The ‘Business Recorder’ and the Daily Khabrain’ of December 14, 2012 issue.

³ “PCT” is the abbreviation for Pakistan Customs Tariff. PCT heading in Pakistan is equivalent to Harmonized Commodity Description and Coding System up to six-digit level.

ii. **Domestic Like Product:**

“the domestically produced product, which is a like product to an investigated product”.

iii. **Like Product:**

“a product which is alike in all respects to an investigated product or, in the absence of such a product , another product which , although not alike in all respects, has characteristics closely resembling those of the investigated product”.

12.2 For the purposes of this investigation and given the definitions set out above, the investigated product, domestic like product and the like product are identified as follows:

12.3 **Investigated Product:**

12.3.1 The investigated product Pegylated Interferon Alpha-2a (Pegasys), injection 180 micrograms per ml imported from Switzerland. PEGASYS is a sterile, preservative-free, colorless to light yellow injectable solution administered subcutaneously. Pegylated Interferon Alfa-2a is produced using recombinant DNA technology in which a cloned human leukocyte interferon gene is inserted into and expressed in *Escherichia coli*.

12.3.2 Pegylated Interferon Alfa-2a is an antiviral drug discovered at the pharmaceutical company F. Hoffmann-La Roche; it has a dual mode of action - both antiviral and on the immune system. Interferons (IFNs) are proteins made and released by host cells in response to the presence of pathogens (infectious agents) *such as viruses, bacteria, parasites or tumor cells*. They allow for communication between cells to trigger the protective defenses of the immune system (*The immune system is a system of biological structures and processes within an organism that protects against disease*) that eradicate pathogens or tumors.

12.3.3 Pegylated Interferon Alfa-2a is a polyethylene glycol (PEG)-modified form of human recombinant interferon Alfa-2a intended for the treatment of adult patients with chronic hepatitis C (CHC) or chronic hepatitis B (CHB).It is classified under PCT heading Nos. 3002.2090. For optimal use of Pegylated Interferon Alfa-2a in patients with chronic Hepatitis C, it is used in combination with ribavirin.

12.4 **Domestic Like Product**

The domestic like product is Pegylated Interferon Alpha-2a, injection 180 micrograms per ml. It is classified under PCT heading Nos. 3002.2090. It is used for treatment of Chronic Hepatitis C and (CHC) and Chronic Hepatitis B (CHB). Major uses of the domestic like product are, therefore, identical to those of the investigated product.

12.5 Domestic Like Product is a Bio-similar product. Bio-similar or follow-on biologics are terms used to describe officially approved subsequent versions of innovator bio-pharmaceutical products made by a different sponsor. Bio-similar re-manufacturers do not have access to the originator's molecular clone and original cell bank, nor to the exact fermentation and purification process, nor to the active drug substance. They do have access to the commercialized innovator product.

12.6 Like Product:

12.6.1 Pegylated Interferon Alpha-2a, injection 180 micrograms per ml imported from Switzerland and that produced by the domestic industry is like product, as both are classified under same PCT heading Nos. 3002.2090. Both are used for treatment of Chronic Hepatitis C and (CHC) and Chronic Hepatitis B (CHB).

12.6.2 In order to establish whether the investigated product, the domestic like product and the like product are alike products, as contended by the Applicant, the Commission reviewed all relevant information received/obtained from various sources including the Applicant and exporter/producer in the following terms:

- i. raw materials used in the production of the investigated product, the domestic like product, and the like product are same/similar;
- ii. all the three products have similar applications;
- iii. all the three products are substitutable in use. and;
- iv. all the three products are classified under the same PCT/HS heading No. 3002.3090.

12.7 In light of the above, the Commission has determined that the investigated product, the domestic like product and the like product are alike products.

13. Period of Investigation

13.1 In terms of Section 36 of the Ordinance, period of investigation (hereinafter referred to as "POI") is:

- i. *"for the purposes of an investigation of dumping, an investigation period shall normally cover twelve months preceding the month of initiation of the investigation for which data is available and in no case the investigation period shall be shorter than six months."*
- ii. *"for the purposes of an investigation of injury, the investigation period shall normally cover thirty-six months:*
"Provided that the Commission may at its sole discretion, select a shorter or longer period if it deems it appropriate in view of the available information regarding domestic industry and an investigated product".

13.2 POI selected for dumping and injury are, therefore, as follows:

For determination of dumping: From October 1, 2011 to September 30, 2012
For determination of material injury: From July 1, 2010 to September 30, 2012

14. Information/Data Gathering

14.1 The Commission sent the Exporter's Questionnaire on December 19, 2012 to the exporter/producer of the investigated product from Switzerland for submission of data and information. The exporter/producer was asked to provide requisite data within 37 days of the dispatch of the Questionnaires i.e. by January 24, 2013.

14.2 The exporter replied to the Commission's letter on January 17, 2013 that they are not willing to respond to the exporter's questionnaire. The Commission however, sent reminders to the exporter/producer on January 31, 2013. The Commission did not receive any response to the questionnaire from the exporter/producer. The exporter was informed on March 14, 2013 that in case it does not provide requisite information, the Commission would rely on best information available in terms of Section 32 of the Ordinance to make preliminary or final determination in this investigation.

14.3 The Commission also requested on December 19, 2012 other domestic producer of the domestic like product i.e. BF Biosciences (BFB) to provide requisite information on the prescribed questionnaire. The Commission received response of BFB on January 24, 2013. The deficiencies were communicated to the BFB (the other domestic producer) to acquire the deficient data.

14.4 The Commission asked the importer of the investigated product from Switzerland i.e. Roche Pakistan Limited (RPL) to provide information on Importer's Questionnaire. The importer sought several extensions in time period for submission of information, which were granted on the basis of good cause shown. RPL submitted filled-in Importer's Questionnaire on February 12, 2013. The information submitted in the Importer's questionnaire has been examined and the deficiencies found in it were communicated to the RPL on February 25, 2013. In response RPL provided the deficient information.

14.5 Thus, the Commission has sought from all available sources the relevant data and information deemed necessary for the purposes of this investigation to determine dumping of the investigated product and injury to the domestic industry caused therefrom. In terms Sections 32(4) and 35 of the Ordinance and Rule 12 of the Rules, the Commission has satisfied itself to the accuracy of information supplied by the interested parties to the extent possible for the purposes of this investigation.

15. Questionnaire(s) Response by the M/s Hoffmann-La Roche, Switzerland

15.1 The Commission sent Questionnaire to Hoffmann-La Roche, Switzerland, (hereinafter referred to as "the Exporter") on December 19, 2012. In response the exporter informed the Commission that it would not respond to the NTC's Exporter's Questionnaire, as the exporter and the importer are subsidiaries of one parent company i.e. Roche Holding Limited, therefore, the response of the importer should be considered as the response of the exporter.

15.2 The Commission informed the exporter that the nature of data required from the exporter/producer is different from that of the importer. Further, the Commission informed the importer for provision of data/information relating to the exporter.

15.3 The Commission did not receive any information on Exporter's Questionnaire either from the Exporter or by the Importer. Therefore, the Commission relied on the best available information for purpose to calculate dumping margin.

16. Verification of the Information

16.1 In terms of Sections 23 and 35 of the Ordinance and Rule 12 of the Rules, during the course of an investigation, the Commission shall satisfy itself as to the accuracy of the information and verify/examine the accuracy of the information supplied by the Applicants.

16.2 In order to verify the information/data provided by the Applicant and M/s BF Biosciences and to obtain further information, on-the-spot investigations were conducted at the offices and plants of the Applicant and M/s BF Biosciences from February 6 to 7, 2013 and May 2 to 3, 2013 respectively.

17. Public File

The Commission, in accordance with Rule 7 of the Rules, has established and maintained a public file at its offices. This file remained available to the interested parties for review and copying from Monday to Thursday between 1100 hours to 1300 hours throughout the investigation (except public holidays). This file contains non-confidential versions of the application, response to the Questionnaires, submissions, notices, on-the-spot investigation reports, preliminary determination, record of hearing, comments of interested parties, statement of essential facts, correspondence, and other documents for disclosure to the interested parties.

18. Confidentiality

18.1 In terms of Section 31 of the Ordinance, the Commission shall keep confidential any information submitted to it, which is by nature confidential, or determined by the Commission to be of confidential nature for any other reason, or provided as confidential by parties to an investigation, upon good cause shown, to be kept confidential.

18.2 The Applicant, the other unit in domestic industry and the importer requested to keep confidential the information, which is by nature confidential in terms of Section 31 of the Ordinance. This information includes data relating to sales, sale prices, cost to make and sell, inventories, production, profit/(loss), return on investment, cash flow, growth, investment, salaries & wages, number of employees and capacity. In addition to this, the Applicants and other interested parties also provided certain information on confidential basis, as its disclosure would cause adverse effect upon them.

18.3 Pursuant to requests made by the Applicant and other interested parties to treat certain information as confidential, the Commission has determined confidentiality in light of Section 31 of the Ordinance and for the reasons that disclosure of such information may be of significant competitive advantage to a competitor, or because its disclosure would have a significant adverse effect upon the interested parties providing such information.

18.4 However, in terms of Sub-Section (5) of Section 31, non-confidential summaries of all confidential information, which provides reasonable understanding of the substance submitted in confidence, were placed in public file.

B. DETERMINATION OF DUMPING

19. Dumping

In terms of Section 4 of the Ordinance dumping is defined as follows:

“an investigated product shall be considered to be dumped if it is introduced into the commerce of Pakistan at a price which is less than its normal value”.

20. Normal Value

- 20.1 In terms of Section 5 of the Ordinance “normal value” is defined as follows:
- “a comparable price paid or payable, in the ordinary course of trade, for sales of a like product when destined for consumption in an exporting country”.*
- 20.2 Further, Section 6 of the Ordinance states:
- “(1) when there are no sales of like product in the ordinary course of trade in domestic market of an exporting country, or when such sales do not permit a proper comparison because of any particular market situation or low volume of the sales in the domestic market of the exporting country, the Commission shall establish normal value of an investigated product on the basis of either:*
- “(a) the comparable price of the like product when exported to an appropriate third country provided that this price is representative; or*
- “(b) the cost of production in the exporting country plus a reasonable amount for administrative, selling and general costs and for profits.*
- “(2) Sales of a like product destined for consumption in domestic market of an exporting country or sales to an appropriate third country may be considered to be a sufficient quantity for the determination of normal value if such sales constitute five per cent or more of the sales of an investigated product to Pakistan:”.*
- 20.3 Ordinary course of trade is defined in Section 7 of the Ordinance as follows:
- “(1) The Commission may treat sales of a like product in domestic market of an exporting country or sales to a third country at prices below per unit, fixed and variable, cost of production plus administrative, selling and other costs as not being in the ordinary course of trade by reason of price and may disregard such sales in determining normal value only if the Commission determines that such sales were made –*
- “(a) within an extended period of time which shall normally be a period of one year and in no case less than a period of six months;*
- “(b) in substantial quantities; and*
- “(c) at prices which do not provide for the recovery of all costs within a reasonable period of time.*
- “(2) For the purposes of sub-clause (b) of sub-section (1), sales below per unit cost shall be deemed to be in substantial quantities if the Commission establishes that –*
- “(a) a weighted average selling price of transactions under consideration for the determination of normal value is below a weighted average cost; or*
- “(b) the volume of sales below per unit cost represents twenty per cent or more of the volume sold in transactions under consideration for the determination of normal value.*
- “(3) If prices which are below per unit cost at the time of sale are above the weighted average cost for the period of investigation, the Commission shall*

consider such prices as providing for recovery of costs within a reasonable period of time.”

21. Export Price

The “export price” is defined in Section 10 of the Ordinance as “*a price actually paid or payable for an investigated product when sold for export from an exporting country to Pakistan*”.

22. Dumping Determination

22.1 As stated earlier, the Applicant has identified only one exporter/foreign producer i.e. F. Hoffmann-La Roche, from Switzerland involved in alleged dumping of the investigated product. The Commission sent Questionnaire directly to the exporter/foreign producer. However, no data/information has been provided by the exporter/ foreign producer. Therefore, the Commission has relied on the best available information for calculation of dumping margins under Section 32 of the Ordinance.

22.2 Determination of Normal Value

22.2.1 As stated earlier the Commission had to rely on the best information available for calculation of dumping margin due to non-cooperation of the exporter i.e. F. Hoffmann-La Roche, Switzerland. To calculate normal value for the exporter the Commission has used construction of cost to make and sell method in terms of Section 6(b) of the Ordinance using best information available as envisaged in Section 32 of the Ordinance. In this regard, cost to make and sell of domestic producers of the domestic like product has been used and is adjusted for costs in Switzerland on the basis of data collected from IMF data, World Electricity Price Index.

22.3. Determination of Export Price

22.3.1 As mentioned earlier that the exporter of the investigated product has not cooperated with the Commission therefore, the Commission has to rely on the best information available for determination of export price to calculated dumping margin.

22.3.2 Though the exporter/producer of the investigated product i.e. F. Hoffmann-La Roche, has not cooperated however, its related company in Pakistan, Roche Pakistan Limited has cooperated with the Commission and has provided information in the importer questionnaire. Export price has been calculated on the basis of information provided by Roche Pakistan Limited. To arrive at ex-factory export price, for fair comparison, ocean freight, inland freight and other miscellaneous expenses (works out to be fifteen percent as per information provided by the Applicant on the basis of data collected relating to exports by the Exporter to India) has been deducted from the C & F price.

22.4 Dumping Margin

22.4.1 The Ordinance defines “dumping margin” in relation to a product to mean “the amount by which its normal value exceeds its export price”. In terms of Section 14(1) of the Ordinance the Commission shall determine an individual dumping margin for each known exporter or producer of an investigated product.

22.4.2 The requirements of Section 11 of the Ordinance has been met which states that “the Commission shall, where possible, compare export price and normal value with the same characteristics in terms of level of trade, time of sale, quantities, taxes, physical characteristics, conditions and terms of sale and delivery at the same place which shall be normally at ex-factory level”.

22.4.3 Taking into accounts all the above-mentioned requirements dumping margin as percentage of adjusted export price comes to 32.45 percent and as percentage of C & F export price comes to 27.58 percent.

23. Negligible Volume of Dumped Imports

23.1 In terms of Section 41(3) (b) of the Ordinance, volume of dumped imports shall normally be regarded as negligible if the volume of dumped imports of an investigated product is found to account for less than three percent of total imports of the like product unless imports of the investigated product from all countries under investigation which individually account for less than three percent of the total imports of a like product collectively account for more than seven percent of imports of a like product.

23.2 In this regard, data and information available with the Commission on volume of dumped imports of the investigated product from Switzerland and like product from other sources during the POI is given in the following table:

Table-II

Volume of Imports During Oct. 1, 2011 to Sep. 30, 2012

Imports from:	Percentage of Total Imports
Switzerland	100%
Other Sources	0%
Total	100%

Source: PRAL and RPL (Importer of Investigated Product)

23.3 The above table shows that the volume of dumped imports of the investigated product from Switzerland was well above the negligible threshold (less than three percent of volume of total imports of the like product) during the POI.

C. INJURY TO DOMESTIC INDUSTRY

24. Determination of Injury

24.1 Section 15 of the Ordinance sets out the principles for determination of material injury to the domestic industry in the following words:

“A determination of injury shall be based on an objective examination of all relevant factors by the Commission which may include but shall not be limited to:

- “a. volume of dumped imports;*
- “b. effect of dumped imports on prices in domestic market for like products; and*

“c. consequent impact of dumped imports on domestic producers of such products...”

24.2 Section 15 of the Ordinance further provides that:

“ No one or several of the factors identified shall be deemed to necessarily give decisive guidance and the Commission may take into account such other factors as it considers relevant for the determination of injury”.

24.3 The Commission has taken into account all factors in order to determine whether the domestic industry suffered material injury during the POI. Material injury to the domestic industry has been analyzed in the following paragraphs in accordance with Part VI of the Ordinance.

25. **Domestic Industry**

25.1 For the purposes of this investigation, the Commission has determined domestic industry manufacturing domestic like product consisting of the following two units:

- i. Getz Pharma (Pvt) Limited, Karachi;
- ii BF Biosciences, Lahore;

25.2 Application has been filed by one unit i.e. Getz Pharma (Pvt) Limited, Karachi. Other unit, BF Biosciences, Lahore has supported the application and provided all relevant data/information relating to injury to the domestic industry for the purposes of this investigation.

25.3 Analysis of injury to the domestic industry carried out in this preliminary determination in the following paragraphs is, therefore, based on the information submitted by both the units of the domestic industry.

26. **Volume of Dumped Imports**

Facts

26.1 With regard to the volume of dumped imports, in terms of Section 15(2) of the Ordinance, the Commission considered whether there has been a significant increase in dumped imports, either in absolute terms or relative to the production of the domestic like product during the POI.

26.2 In order to ascertain the volume of dumped imports of the investigated product and production of the domestic like product, information submitted by the Applicant, BFB and importer i.e Roche Pakistan Ltd., has been used. The following table shows imports of the investigated product and production of the domestic like product during the POI for injury:

Table-III
Volume of Imports and Domestic Production

Year*	Dumped Imports	Domestic Production**
Jul-Sep 2010	100	18.36
2010-11	396	198
2011-12	565	529

Note: Actual figures have been indexed with reference to the figure of dumped imports of Jul-Sep 2010 by taking it equal to 100.

*October 1 to September 30

** Production of both the units in the domestic industry

Analysis

26.3 Imports of the investigated product, in absolute terms, decreased by 1 percent in 2010-11 as compared to July-September 2010 (if seen on annualized basis). However, it increased by 42.67 percent in 2011-12 as compared to 2010-11.

26.4 Volume of dumped imports was 545 percent of domestic production during July-September 2010. While in 2010-11, volume of dumped imports decreased to 200 percent of domestic production. In 2011-12, volume of dumped imports as percentage of domestic production further decreased to 107 percent.

Conclusion

26.5 On the basis of the above information and analysis, the Commission has concluded that the dumped imports of the investigated product increased in absolute terms during 2011-12.

27. Price Effects

27.1 Effect of dumped imports on sales price of domestic like product has been examined to establish whether there was significant price undercutting (the extent to which the price of the investigated product was lower than the price of the domestic like product), price depression (the extent to which the domestic industry experienced a decrease in its selling prices of domestic like product over time), and price suppression (the extent to which increased cost of production could not be recovered by way of increase in selling price of the domestic like product). Price effects have been determined on domestic industry's information on prices.

27.2 Price undercutting

Facts

27.2.1 Weighted average ex-factory price of the domestic like product has been calculated from the information submitted by the domestic industry on quantity and value of sales during the POI. Average sales price of investigated product to an independent buyer has been calculated from the information obtained from RPL. Comparison of weighted average ex-factory price of the domestic like product with the average sales price of investigated product charged by RPL from an independent buyer during the POI is given in following table:

Table-IV
Calculations of Price Under-cutting

Period*	Average Price of Domestic Like Product	Average Sales Price of Dumped Imports to Independent Buyer	Price Undercutting
Jul-Sep 2010	100	150	--
2010-11	89	117	--
2011-12	46	79	--

Note: Actual figures have been indexed with reference to the figure of average price of domestic like product of Jul-Sep 2010 by taking it equal to 100.

*October 1 to September 30

Analysis

27.2.2 The above table shows that average sales prices of the investigated product to independent buyers were higher than the prices of the domestic like product during the POI. Average price of domestic like product however kept on declining during the POI.

27.2.3 The Applicant claimed that exporter from the Switzerland is an inventor of this product and domestic industry producing bio-similar of Pegylated Interferon Alpha-2a are new entrant in the market and have to offer its product at the price lower than the price of generic product. Another reason is the behavior of consumers and doctors/consultants, who normally prefer imported drugs. As the domestic industry entered into the production, the exporter started offering its product at much lower price. Resultantly, the domestic industry had to further reduce its price to capture the growing competitive market.

Conclusion

27.2.4 On the basis of the above facts and analysis, the Commission has concluded that the domestic industry did not suffer price undercutting during the POI. However, in order to establish its market for a bio similar product the domestic industry kept its price lower than the investigated product.

27.3 Price Depression

Facts

27.3.1 The weighted average ex-factory price of the domestic like product during the POI is given in the table below:

Table-V
Calculation of Price Depression

Period*	Average Price of Domestic Like Product	Increase/(Decrease) in Price
Jul-Sep 2010	100	--
2010-11	89	(11)
2011-12	46	(43)

Note: Actual figures have been indexed with reference to the figure of average price of domestic like product of Jul-Sep 2010 by taking it equal to 100.

*October 1 to September 30

Analysis

27.3.2 Analysis of the above facts shows that domestic industry has continuously decreased the weighted average ex-factory price of domestic like product during the POI, due to drastic decline in the price of the investigated product. The above table shows that the domestic industry decreased price of the domestic like product by 11 percent during 2010-11 and by 48 percent during 2011-12. To compete with dumped imports of the investigated product, the domestic industry was forced to reduce its prices.

Conclusion

27.3.3 The Commission has concluded on the basis of the above information and analysis that the domestic industry has suffered price depression during the POI mainly due to dumped imports of the investigated product.

27.4 Price Suppression

Facts

27.4.1 Weighted average cost to make and sell of the domestic like product has been calculated from the information submitted by the Applicant and the other domestic producer i.e. BFB on the basis of actual cost to make and sell during the POI. The following table shows the weighted average cost to make and sell and the weighted average ex-factory sales price of the domestic like product during the POI:

Table-VI

Calculations of Price Suppression

Period*	Average cost to make and sell of Domestic Like Product	Average Price of Domestic Like Product	Increase/(decrease) Cost	Increase/(decrease) Price
Jul-Sep 2010	83	100	--	--
2010-11	77	89	(6)	(11)
2011-12	71	46	(6)	(43)

Note: Actual figures have been indexed with reference to the figure of average price of domestic like product of Jul-Sep 2010 by taking it equal to 100.

*October 1 to September 30

Analysis

27.4.2 The above table shows that the weighted average cost to make & sell of the domestic like product decreased by 7.23 percent, whereas the weighted average sales price decreased by 11 percent in 2010-11. During the 2011-12 weighted average cost to make & sell of the domestic like product decreased by 8 percent, whereas the weighted average sales price decreased by 48 percent. Though the legal definition of price suppression is that when increased cost of production could not be recovered by way of increase in selling price, however, the above table shows that cost to make and sell of the domestic industry decreased during the POI but the decrease in price was more than decrease in costs mainly because of continuous decrease in the price of investigated product. It also shows that domestic industry's cost to make and sell has been decreasing during the POI.

Conclusion

27.4.3 On the basis of the above information and analysis, the Commission has concluded that the domestic industry suffered on account of decrease in price more than decrease in cost to make & sell during 2011-12.

28. Effects on Market Share

Facts

28.1 Domestic demand for Pegylated Interferon Alpha-2a in Pakistan was met through sales by the domestic industry and by imports. The domestic market of Pegylated Interferon Alpha-2a has been ascertained by combining the domestic industry's sales and total imports. The Applicant and BFB supplied information of their respective sales of domestic like product in domestic market during the POI. Information on imports of

Pegylated Interferon Alpha-2a has been ascertained from data provided by Roche Pakistan Ltd. The total domestic market for Pegylated Interferon Alpha-2a during the POI is given in following table:

**Table -VII
Market Share**

Period*	Sales of Domestic Industry	Imports from Switzerland	Total Size	Market Share
Jul-Sep 2010	9	91	100	9%
2010-11	139	363	502	28%
2011-12	434	517	951	46%

Note: Actual figures have been indexed with reference to the figure of total domestic market of Jul-Sep 2010 by taking it equal to 100.

*October 1 to September 30

Analysis

28.2 The above table shows that domestic market of Pegylated Interferon Alpha-2a increased by 26 percent in 2010-11 as compare to the quarter July-September 2010 (if seen on annualized basis) and 89 percent in 2011-12 as compare to 2010-11. In this growing market, share of domestic industry increased from 9 percent in the quarter July-September 2010 to 28 percent in 2010-11 and to 46 percent in 2011-12. A decline can be seen in market share of the dumped imports from 91 percent in quarter July-September 2010 to 72 percent in 2010-11. It further decreased to 54 percent in 2011-12.

28.3 As stated above the domestic market of Pegylated Interferon Alpha-2a has increased due to decrease in the prices during the POI and it appears that now the CHB and CHC patients who were using simple interferon daily dose (which has more side effects) can afford Pegylated Interferon Alpha-2a. In this situation of intense price competition between investigated product and domestic like product the domestic industry has gained market share by keeping its prices thirty percent lower than the prices of investigated product, thus suffering losses.

Conclusion

28.4 On the basis of above information and analysis, the Commission has concluded that the domestic industry did not suffer on account of market share due to imports of the investigated product during the POI.

29. Effects on Sales

Facts

29.1 As per information obtained from the domestic industry, total sales of the domestic like product by the domestic industry during the POI are as follows:

**Table -VIII
Sales by the Domestic Industry**

Period*	Sales of Domestic Industry
Jul-Sep 2010	100
2010-11	1,639
2011-12	5,100

Note: Actual figures have been indexed with reference to the figure of sales of Jul-Sep 2010 by taking it equal to 100.

*October 1 to September 30

Analysis

29.2 The above table shows that the sales of the domestic like product by the domestic industry increased by 309 percent in 2010-11 as compared to quarter July-September 2010 (if seen on annualized basis) and by 211 percent during 2011-12. The domestic industry sold its increased production by keeping prices substantially lower than price at which the investigated product was resold to independent buyers.

Conclusion

29.3 On the basis of above information and analysis, the Commission has concluded that sales of the domestic like product increased during the POI, hence domestic industry did not suffer material injury on account of sales. However, this increase in sales was due to the fact that domestic industry kept its prices substantially lower than the sales prices of the investigated product during the POI.

30. Effects on Production and Capacity Utilization**Facts**

30.1 Quantity produced and the capacity utilized by the domestic industry during the POI was as follows:

Table-IX
Production and Capacity Utilization

Period*	Capacity Utilization (%)
Jul-Sep 2010	3.4
2010-11	9.3
2011-12	24.8

*October 1 to September 30

Analysis

30.2 Above table shows that the capacity utilization of the domestic industry was 3.4 percent in quarter July-September 2010 which increased to 9.3 percent in 2010-11 and 24.8 percent in 2011-12. The domestic industry has been operating at a very low capacity utilization level.

Conclusion

30.3 On the basis of the above information and analysis, the Commission has concluded that the domestic industry did not suffer on account of capacity utilization, as its capacity utilization improved during the POI.

31. Effects on Inventories**Facts**

31.1 The domestic industry provided data relating to its inventories of the domestic like product during the POI. Data for opening and closing inventories for the domestic like product of the domestic industry during the POI is given in the following table:

Table-X
Inventories of Domestic Like Product

Period*	Opening Inventories	Closing Inventories
Jul-Sep 2010	0	100
2010-11	100	613
2011-12	613	1,200

Note: Actual figures have been indexed with reference to the figure of closing inventory of Jul-Sep 2010 by taking it equal to 100.

*October 1 to September 30

Analysis

31.2 The data given in the table above shows that the inventory level of the domestic like product increased at the end of 2011-12. During this period the production of the domestic industry increased by 167 percent and its sales increased by 211 percent, however, its closing inventories increased by 96 percent.

Conclusion

31.3 On the basis of the above facts and analysis, the Commission has concluded that the domestic industry suffered material injury on account of increase in inventories of the domestic like product during the POI.

32. Effects on Profits/Loss

Facts

32.1 Profit and loss position for the domestic industry has been established on the basis of the information supplied by the domestic industry i.e. its Profit and Loss Account Statements. Both the domestic units are the multi-product companies. Effect on profits is determined on the basis of production and sales of the domestic like product during the POI. Table below shows the yearly profit and loss position of the domestic industry during the POI:

Table -XI
Profit/(Loss) of the Domestic Industry

Period*	Net Profit/(Loss)
Jul-Sep 2010	(100)
2010-11	1,193
2011-12	(7,636)

Note: Actual figures have been indexed with reference to the figure of Jul-Sep 2010 by taking it equal to 100.

*October 1 to September 30

Analysis

32.2 Above table shows that the domestic industry earned net profit during 2010-11. However, it incurred losses in 2011-12.

Conclusion:

32.3 On the basis of the above facts and analysis, the Commission has concluded that the domestic industry suffered material injury on account of incurring losses mainly because of dumped imports of investigated product.

33. Effects on Cash Flow

Facts

33.1 The cash flow position through operating activities of the domestic industry was determined on the basis of the information provided by the domestic industry. Net cash flow position of the domestic industry during the POI is given in the following table:

Table -XII
Cash Flow Position

Period*	Cash inflow/(outflow) from Operations
Jul-Sep 2010	(100)
2010-11	(250)
2011-12	(677)

Note: Actual figures have been indexed with reference to the figure of Jul-Sep 2010 by taking it equal to 100.

*October 1 to September 30

Analysis

33.2 The above table shows that the net cash flow of the domestic industry, remained negative through out the POI.

Conclusion

33.3 On the basis of the above, the Commission has concluded that the domestic industry has suffered material injury on account of cash flows.

34. Effects on Employment, Productivity and Salaries & Wages

Facts

34.1 Effects on employment, productivity and salaries & wages are ascertained on the basis of the domestic industry's information. The domestic industry's employment, productivity, salaries and wages for production of the domestic like product were as follows during POI:

Table -XIII
Employment, Productivity and Salaries & Wages

Period*	Number of Employees	Total Salaries and Wages Paid	Productivity per worker
Jul-Sep 2010	100	100	100
2010-11	109	616	248
2011-12	201	992	358

Note: Actual figures have been indexed with reference to the figures of Jul-Sep 2010 by taking them equal to 100.

*October 1 to September 30

** On annualized basis

Analysis

34.2 The above table shows that the employment in the domestic industry increased during the POI along with the increase in the production of domestic like product. The productivity per worker also increased.

Conclusion

34.3 Based on the above information and analysis, the Commission has concluded that the domestic industry did not suffer on account of employment and wages and salaries and productivity.

35. Effects on Return on Investment

Facts

35.1 Return on investment realized by the domestic industry during the POI is determined on information provided by the domestic industry. Following table shows the investment and return on investment of the Applicant during POI:

Table -XVI
Investment and Return on Investment

Period*	Investment	Return on Investment
Jul-Sep 2010	100	100
2010-11	512	(66)
2011-12	552	(1628)

Note: Actual figures have been indexed with reference to the figures of Jul-Sep 2010 by taking them equal to 100.

*October 1 to September 30

Analysis

35.2 The domestic industry made substantial investment during the POI and was generating negative returns. During the 2010-11 and 2011-12 the domestic industry experienced negative return on investment.

Conclusion

35.3 Based on the above information and analysis, the Commission has concluded that the domestic industry suffered on account of return on investment.

36. Effects on Growth and Investment

36.1 The domestic industry is of the view that it has recently made substantial investment in the business of the domestic like product and has the capacity to cater the domestic demand. Therefore there is no prospective for further investment in the business of domestic like product.

37. Summing up of Material Injury

37.1 The facts and analysis in the preceding paragraphs (paragraphs 26 to 39 supra) shows that the domestic industry has suffered material injury during POI on account of:

- i) Increase in volume of dumped imports in absolute terms;
- ii) price depression;
- iii) losses;
- iv) negative return on investment,
- v) negative effects on inventories; and
- vi) negative effect on cash flow;

37.2 The volume of dumped imports grew during the POI in absolute terms but did not grow relative to domestic production. The domestic production of domestic like product grew with much faster pace than the dumped imports. No price undercutting and price suppression was found during the POI. The domestic industry faced price depression but that was also partially due to decrease in cost to make and sell. Market share of the domestic industry grew during the POI in comparison with the dumped imports. However, the domestic industry faced losses, negative return on investment, high inventories, low capacity utilization and negative effects on cash flow during the POI.

37.3 Before establishment of the domestic industry of the domestic like product 100 percent share was with the investigated product. With the introduction of the domestic like product the investigated product started losing its share in the Pakistani market. To avoid that the importer started reducing prices of the domestic product. The data provided by the importer shows that the C & F price of the investigated product was 39 percent higher than the price at which it is sold to independent customers in Pakistan during POI. This behavior of the importer forced the domestic industry to reduce the price of domestic like product. Though market share of the domestic like product grew due to reduction in prices but it was at the expense of losses .

37.3 It is, therefore, concluded that the domestic industry suffered material injury on account of some factors due to dumped imports of the investigated product.

38. Other Factors

38.1 In accordance with Section 18(2) of the Ordinance, the Commission also examined factors, other than dumped imports of the investigated product, which could at the same time cause injury to the domestic industry, in order to ensure that possible injury caused by other factors is not attributed to the dumped imports.

38.2 The Commission's investigation showed that the domestic industry is also facing tariff anomaly on imports packing materials for packaging of Pegylated Interferon Alpha-2a. The investigated product is being imported in finished form (after packaging) at duty free rate. Whereas, the packing material of the domestic like product has to be imported at the rate of 15 percent, which affects the competitiveness of domestic like product. However, injury caused by this anomaly cannot be considered significant.

D. CAUSATION

39. Effect of Dumped Imports

On the basis of the analysis and conclusions, the Commission has concluded that there was a causal link between dumped imports of the investigated product and material injury suffered by the domestic industry. The investigation revealed that the following happened simultaneously during POI:

- i. The importer's behavior of selling the investigated product to independent customer in Pakistan by 39 percent below the C & F price, created pressure on price of the domestic like product which led to price depression though

the domestic industry became efficient and there was reduction in its cost to make & sell but reduction in price of domestic like product was even more than reduction in its cost to make & sell;

- ii. Domestic industry incurred losses on production of the domestic like product due to dumped imports of the investigated product during POI for dumping; and
- iii. Domestic industry could not utilize capacity up to a reasonable level, resultantly it suffered on account increased fixed costs during the POI due to dumped imports of the investigated product.

E. CONCLUSIONS

40. The conclusions, after taking into account all considerations for this preliminary determination, are as follows:

- i. the application was filed on behalf of domestic industry as the Applicant represent major proportion of the production of domestic like product;
- ii. The application has been supported by 100 percent of domestic industry producing domestic like product
- iii. the investigated product and the domestic like product are alike products;
- iii. during POI, the investigated product was introduced in the commerce of Pakistan at prices below its normal value;
- iv. the volume of dumped imports of the investigated product and the dumping margin established for the exporter/producer of the investigated product from the Switzerland are above the negligible and *de minimis* levels respectively;
- v. the dumping margins expressed as a percentage of adjusted export price is 32.45 percent and C&F export price is 27.58 percent.
- vi. the domestic industry suffered material injury during POI on account of price depression, low capacity utilization, losses, negative effect on cash flow and negative effect on return on investment in terms of Section 15 and 17 of the Ordinance; and
- vii. there is a causal relationship between dumped imports of the investigated product and the material injury suffered by the domestic industry.

41. In reaching this preliminary affirmative determination, the Commission is of the view that the level of injury is not such which justifies imposition of provisional measures. Pricing mechanism of biosimilars and generic needs to be studied further, to understand price undercutting in this investigation, which is apparently not visible. As the domestic industry entered in the market couple of years back and it is obvious that most of the injury factors would show a positive trends. Therefore, a need is felt that injury may be further investigated to see effects of dumping. No provisional measures are being imposed in this preliminary determination in accordance with Section 43 of the Ordinance as it is less likely that significant injury is being caused during the course of investigation. However, the investigation will be carried on till the final determination of investigation.

(Dr. Allah Bakhsh Malik)
Member
July 23, 2013

(Niamatullah Khan)
Member
July 23, 2013

(Prince Abbas Khan)
Chairman
July 23, 2013