pharmexcil

PHARMACEUTICAL EXPORT PROMOTION COUNCIL

(Set up by Ministry of Commerce & Industry. Govt. of India)

Ref: Pharmexcil/RO/Del/DGFT/07-08

November 26, 2007

Dear Shri Gujralji,

This has reference to your letter under reference No. D.O. No. 01/94/180/FTP-Annual Supp.2008/AM-08/PC-1/3286 dated 2nd November 2007 with regard to suggestions / proposals to the Foreign Trade Policy for the year 2008-09.

We are enclosing herewith our suggestions / proposals to the Foreign Trade Policy for the year 2008-09.

We would like to inform you that Pharmexcil has organized an Open House meet on the occasion of our Annual General Meeting on 28th November 2007 at Hyderabad. We are thankful to you for deputing Dr. Shyam Agarwal, Additional DGFT for the open house at Hyderabad. During the open house meeting on 28th November 2007 some more suggestions / proposals from our members is likely to emerge.

We shall be compiling these suggestions also and submitting the same to you for your perusal and consideration in the FTP Annual Supplement to be announced in March 2008.

We look forward to your consideration of our proposals / suggestions.

With warm regards

Venkat Jasti
Vice-Chairman

Encl: As mentioned above.

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S. No.	Suggestions	Chapter of F.T.Policy / Handbook	Rationale	Effect on Exports	Impact on Industry transaction cost & time	Remarks if any
(01)	Inclusion of Pharma industry in the thrust areas for policy support	Chapter 1b Special Focus Initiatives **(FT Policy)**	Pharma Industry contributes significantly towards the country's total export. This industry offers goods opportunity for employment including technical skilled job. More so in view of R&D & Medical tourism gaining significance	There will be boost in exports of Pharma Products Annual export from India Rs. 141 Billion Future Project Rs. 1200 Billion (By McKinsey) by 2010	Reducing transaction cost and time	ANN-1
(02) D E P B						
	DEPB Scheme should continue	Chapter 4 Para 4.3. DEPB **(FT Policy)**	DEPB Scheme which is transparent simplified and export friendly should continue. Alternative Scheme currently under examination should also contemplate neutralization of other levies like State Excise Duties, Sales Tax , turn over tax, octroi etc.	There will be a continued surge in exports owing to the availability of export-friendly scheme like DEPB		
	Inclusion of Lozenges in the description of Tablets covered under SION and relevant entries of DEPB rate list	S.No A-412 of SION HBP VOI-II	Since Lozenges are only a type of tablet, they are logically included in the existing description. The addition of lozenges to the description of this S.No. is sought to ensure operational facilitation.	To the extent of denial of export support, the exporters have to operate with high transaction costs		ANN-1A
		S.No. 37&42 of DEPB rate list (Chemical)		Due to current omission of lozenges from the description of tablets, exporter of lozenges which for all practical purposes are Pharma Formulation		

				in the form of tablets are unduly denied export support.		
	Additions to DEPB Rate List i) In each of S.No 37,38,39,40,41 & 42 or rate list for chemical products sub entries E & F may be added as follows with DEPB benefits @6% of the DEPB rate of bulk drugs - E-Medicated Creams / Ointments / Gels / Lotions / Liquids - F-Eye / Ear / Nasal Drops	Schedule of DEPB rate for Chemical Products HBP Vol II		Once these formulations are included in the DEPB rate list, it will simplify neutralization of duties which will reduce the transaction time and cost. In the absence of DEPB rates, exporter are compelled to get duty drawback rates fixed from time to time which is tedious and time consuming		ANN-2
ii)	Restoration of earlier DEPB rate of 3% under	Product Code 90 S.No. 22D	The initiative taken by the Minister of Commerce in enhancing the DEPB rates to compensate the loss incurred by the Exporter on account of rupees appreciation was widely welcomed by the Industry. In this move for Product Code 90 S.No. 22D DEPB rate increased to 3% from earlier 1%. This was welcomed by the Industry. Unfortunately, this happiness was taken away by amending the rate to 1.5% vide PN 66/07 – 09.10.07. This move is totally defeated the very purpose of the initiative taken by the Commerce Minister especially in the situation of further appreciated of rupees.		In the alternative, it is requested to notify DEPB rates for all the products covered under SION by removing S.No. 22D under Product Code 90.	
	Clarification on date of up-linking of Shipping detail from custom's server to DGFT server	Para 4.4.6 of HBP Vol-1 PN 56/07	Vide Public Notification No. 56/07 provision of time limit of filing of application without late cut within one year. In DGFT server there is no provision to identify date of such linking-up from Custom Server			ANN-4
	Agency commission 12.5% on FOB Value	4.43 of HBP Vol.1	As per para 4.43 of HBP (Vol-1), the Agency Commission will be allowed upto 12.5% on FOB Value only and not on CIF value. Earlier, 12.5% agency commission was being allowed on CIF value. Latter the same was amended to consider the commission only on FOB. The General Trade practice prevailing in the industry is to pay commission on CIF value and not on FOB. The present position of restricting the agency Commission on FOB Value is creating hardship to the exporters to deduct the extra commission paid	The present position of restricting the Agency Commission on FOB value is creating hardship to the exporter to deduct the extra commision		

			from FOB Values at the time of DEPB applications especially in Formulations where in one Shipping Bill there would more than 10 products and deducting this extra commission product wise is no doubt a Herculean task. Hence, it is requested to amend the para by restoring the earlier practice of allowing the Agency commission on CIF Value.			
(03) Advnace Authorisation / DFIA Scheme						
	Review of SION, as and when done should only be limited to the appropriateness of quantities of inputs allowed to be imported duty free. The review of norms should not preclude import of penultimate state inputs to be converted into finished products for exports	Periodical review of Std Input/ Output Norms	As long as export possibilities can be converted into actual exports, the stage at which any manufacturer begins production activity should be left to be decided by individual manufacturer	In the field of Chemicals, Drugs and Pharmaceutical substantial production in the country is generated by technocrats taking to manufacturing activities, particularly in areas where inputs from various stages can be processed into finished export products. Not allowing penultimate stage inputs would not only deprive any technocrat entrepreneurs from participating in country's export efforts but also adversely impact employment avenues.		Council has submitted representation in context of PN NO. 64/ 24.10.95
	In terms of Policy Circular No. 41 (Re-2005) 2004-09 dated 12.12.05, it has been clarified that in cases where exempt material have been imported under exemption provisions as contained in the above Circular, the procedure of regularization for licenses in the event of failure to complete the export obligation by payment of import duty with interest @15% as provided for in Para 4.28 of HB Policy.	Policy Circular No. 9 dated 30.06.03, 12 dated 27.06.2005 and 41 dated 12.12.2005				ANN-5

- In such cases, the licensee should have the option either to use the imported raw material for production of other export products for export of or to re-export the imported raw material and the advance license obligation shall be deemed to have discharged to that extent.
- There are instances where export orders get cancelled for various reasons after part export have been made. In such instances,

	re-exporting the exempt materials which have been part utilized is not feasible. - The reasons being that the total import quantity may be the minimum tradable lot of the supplier may be unwilling to accept the goods which have been opened and part utilized. To satisfactorily deal with hardships rising out of such situations, a suitable via-media for regularization of such licenses needs to be worked out in consultation with the office of the Drugs Controller General (India). - As the initial export obligation period is only six months, it is suggested that the exporters should be permitted extension of E period for further two years. - When a new molecule is introduced, to standardize the same, the manufacturer requires additional quantity for R&D purposes and hence our submission to you to increase the wastage norms by 3%. This may be applicable to exporters who are importing for the first time from the new source. - Further when any molecule is not registered and it is imported for export production our manufacturer facing difficulty to get and yield of 98% (SION Sr. No. 412 applicable for export products tablets & capsules). It is suggested that in such cases also when export obligation is not fulfilled due to yield problem exporter should be allowed to close file subject to the condition mentioned in policy circular No.18 dt. 30th October 2007					
	Currently there are so many applications lying with DGFT for fixation of I-O Norms. We request that priority may be given for clearing this backlog.	Chapter 4 of FT Policy. Para 4.9 of Handbook				

Clubbing of Advance Licence - request for relaxation of certain conditions of the HB of Procedure:

We invite your kind attention towards 4.20 of HBP deals with facility of clubbing. Following clauses have been inserted in said provision:

- The clubbing would be available only for redemption / regularization and not for further imports or exports.
- Licences should be issued under similar customs NF even pertaining to different financial years.
- There should be shortfall in export obligation in the licences sought to be clubbed and the other licences to be clubbed, which is valid for import (4.20.3)
- The export effected in the subsequent licence beyond the validity of the earlier licence will not be considered for clubbing (4.20.4).
- The provision of 4.20.3 & 4.20.4 will not be applicable for clubbing of all expired licences issued during Policy period 1992.97, 1997 2002 (4.20.5)

In view of above, it is essential that for availing the facility of clubbing the licence with the other licences to be clubbed should be valid for imports and any lichencses which are expired or the exports effected beyond the validity period of the earlier licence can not be clubbed. Further, as per para 4.2.5, facility of clubbing provided for expire licences which are issued during the period 1st April, 1992 to 31st March, 2002 only and not for subsequent period.

Request the Hon'ble DGFT to kindly consider the following issues to be considered and relaxation by amendment to be provided for the existing provisionss.

- Licences issued under different Notifications also to be considered for clubbing, if there is no change in the exemption of similar duties.
- Expired licences issued after 01.04.2002 to 31.03.2004 also to be considered for clubbing.
- If the above points are not considered, provisions of para 4.20.4 to be deleted so that the exports effected beyond the validity

	period of earlier Licence can also be considered for clubbing. Reason for this relaxation is that no exporter will foresee during the validity of the licence period which licence would be clubbed with what licence.
-	Verification of Advance authorization / DFIA should be simplified. Exporter also facing considerable delay in getting shipping bills at the DGFT server from Customs Ice gate. This problem needs to be rectified.
Submission of Consumption Register for Advance Licence / DFIA:-	
-	As per 4.30 of HBP (Vol-1) for all the Advance Licences issued on or after 13.05.2005, submission of consumption register in Appnedix-23 duly certified by Chartered Accountant made mandatory. The Advance Licenses are being issued based n the SION fixed by the DGFT including adhoc norms recommended by ALC (NC). Insisting for submission of Consumption details will lead to increase in Transaction Cost. DGFT being the final authority may review the SION of the products at any time without insisting for the consumption detail. Sir, it is humble suggestion that amend the provision by deleting the mandatory requirement of submission of Consumption detail in Appendix – 23 and dispensed with as Input Output Norms are sufficient to check the misuse.
-	EFT refund of excess application fee debited twice/thrice due to system problem is getting delayed even after the DGFT issued a PN prescribing the procedure for refund. Request to issue further instructions to RLAs for immediate sanction of the refund of the excess EFT amounts in terms of PN 75/09.12.2005.

ANN-6

(04) EPCG SCHEME:

During July 2007 the DGFT considered provision of installation certificate from Chartered Engineer as per PN 22/2007 as requested by Trade, which was welcomed by the trade, as it certainly help the exporter in reducing the transaction cost. Surprisingly this provision was again reversed in October vide PN 54/207 by restoring the earlier provision that Installation certificate by the Central Excise Authorities. Request to Hon'able DGFT to restore the provision issued in July 2007

ANN-7

(05) Serve From India Scheme

Scheme should be extended to all RAW materials and also should be transferable. The current scheme only allow to import consumable and capital goods, which are directly relates to that services exported	3.6.4 & 3.12.5. of F.T.Policy	It will boost the Pharma Technical Services Sector exports			

(06) Focus Market Scheme

It is suggested to include following CIS countries in the countries eligible for Focus Market Scheme. - Russian Federation - Ukraine	Chapter 3 of FTP Para 3.9 (Appendix 37C)	CIS countries are landlocked countries and the mode of transport is by Sea to Land/Rail. Owing to the fragmentation one comes across number of borders leading to customs formalities etc. As these countries face severe winter, the goods could	It will encourage exporter to export their goods to CIS countries.		

			not be transported through a shorter route via Middle East and instead transported via China which is a circuitous route. None of regular shipping lines service these countries. The reason being the haulage cost is more than the cost of containers itself. The forwarders who are giving services include the cost of containers in the freight itself. Ten C.I.S. countries were included last year but Russian Federation and Ukraine were not figuring in the List.			

(07) Target Plus Scheme

- To increase our competitiveness, we should introduce Target Plus Scheme (due to appreciation in Rupee) to give special relief to the Exporter.
- Also earlier licenses / goods procured under said scheme should be transferable

(08) EOU Scheme

	Our earnest request to your that EOU Income Tax benefit should continue for another 5 years after the date of expiry of sunset clause, 31st March 2009	Para 6.12 – Exemption from payment of Income Tax as per the provisions of Section 10A & 10B of I.Tax Act	Benefit of exemption from Income Tax for EOU Unit is a major one. Discontinuing the same from 31.03.2009 shall discourage these units and they may opt for debonding which may affect the country's exports.	There will be reductions in exports as EOU Units may opt for de-bonding.		
	In case of any eventuality EOU benefits are not extended beyond 1st April 2009, then EOU Manufacturers should be allowed to shift their machineries to SEZ [illegible]	Under the above provisions of the Income Tax exemption is available only upto				ANN-8

		31st March 2009				
	Like all other class of Exporters, EOUs too should be exempted from the incidence of Service Tax	Objective & Strategies of F.T.Policy	Levy of Service Tax is not compatible with the Basic concept of EOU Scheme viz. carrying out production for export under full exemption from all types of duties taxes and levies.	To maintain an increase in the contribution of EOUs to overall exports which currentyly is pegged at about 20% by marking their operations cost effective	In direct proportion to the extent of service tax which at the current level 10.2% is quite substantial.	This suggesti on has been pending since 2004-05

(09) Rupees appreciation :

1. Our country has got foreign exchange **reserves of about USD250 billion** and part of this amount is invested in the US Government Bond and some other sovereign countries, whose economies are strong @LIBOR + 0.25% or may be less. Sir our submission is that out of the said reserves, RBI may give certain portion to the various banks in india with proper guidelines and this amount should be disbursed to the Exporter at the concessional rate of interest LIBOR + 0.25% or lower, so that our competitiveness in the global market slightly goes up. ANN

2. At present interest subvention of 2% per annum is available to a list of eleven sectors and SME. All sectors including pharmaceutical sector should be also included in this scheme.

(Copy of representation sent to Mr. G.K. Pillai, Secretary, Deptt. Of Commerce enclosed) ANN-

(10) Exchange Rates :

	Exchange Rates		As a relief measures to exporters in view of strong rupee, it is suggested that dual exchange rates be introduced by RBI. Exporter may be allowed to convert their dollar realization at Rupee 42/-			

(11) MDA/MAI

- Apart from registration fees, expenses involved in generating dossiers like clinical trials, professional fees and visits of personal of registering authorities for plant audit are included for reimbursement.
- Expenses on obtaining certificates of suitability for marketing APIs in Europe should be qualified for reimbursement as product registration fees.
- All fees paid to registering authorities viz. part payment with filing of application and balance on completion of registration process should be computed as registration fess even when such payments have been made in different financial years.
- MAI for Direct Participation in Exhibitions : MAI should be made available for fairs where companies want to participate directly also. This is because Pharmexcil is participating in fairs, which they consider important at large, but individual exporter may have priority in another sector/country.
- Faster Refunds: Refund of MAI for registration cost should be faster and smooth

- Reimbursement of registration of products should also include :Bio-equivalence test, stability test etc which have done to get the products registered in various countries. The expenses of getting these tests done are very expensive.
- Incentives for Brand promotion : Special Incentive should be given to exporter for single brand value generated more than Rs. One Crore during a financial year. This will motivate exporters to build brands, which have long duration of exports.
- Enhancing reimbursement of travel expenses: Reimbursement of travel expenses should be increased to 100% . Logic is the more we travel the more we know our customer and the more revenue we will bring. And the growth we achieved is just a penny @ 21%, is nothing. Because the opportunities is still lying in Latin American countries is not utilized due to heavy travel and other related expenses.
- Facilitating 100% Reimbursement: As we all know the products registration 50% reimbursement is also not meeting much more purpose because apart from official fee we have arrange to pay miscellaneous fee which is quite high. So the Re-imbursement must be 100% to utilize the best salesmanship of Indians
- MDA scheme has been simplified and very easy to operate. Similarly MAI scheme should be simplified and the reimbursement of product registration charges to the Exporters should be operated through the Council with the normal checks and balances as in MDA schemes.
- Upgradation of facilities like HVAC systems, Water systems, other Quality Control, Methodology and Validation etc.
- Contract Research
- Brand Equity, Biotechnology, Medicinal Plant Research.

(12) Other Issues :

01	Manufacturers who have established a Brand Equity are facing a problem of counterfeit & Fake Drugs Exports. Merchant Exporters have played a pivotal role in increasing export of all commodities but as far as Pharmaceutical products are concerned, there is need to prevent the counterfeit & Fake drugs exports. Our suggestions in this regard as follows:	Export of Counterfeit & Fake drugs	We have received lot of complaints from our members that counterfeit & fake drugs are exported from India with identical labels of the products. However, the contents in products are not as per the formula for the well known brand. Therefore there is need to strengthen the procedure.			

1. Invoice from the manufacturers that the products have been from them.
2. Certificate of Analysis.
3. Registration Certificate if the registration certificate is applicable in the importing country.
4. Central Excise Gate-Pass.
5. NOC from the Manufacturers.

This should be become a part of the Foreign Trade Policy

02	Lifting of additional duty on importation of equipments mean for Pharma & Bio Technology sector **(Para 2.55 of HBP Vol-1)** - Initially the equipments imported under the above provision were exempted total customs duties and later the Govt imposed CVD on import clearance of such R&D equipments. This imposition of CVD will defeat the very purpose of the facility which was given the R&D activities carried out in the Pharmaceutical Bio-Technology sectors. Because of this imposition of CVD, the scheme is not being utilized by many companies. Request for consideration inremoving the CVD and restore the earlier provision. - Also the equipments mentioned in the said list are too old and has the limited scope of usage today. Whereas there are so

	many other modern instruments, which are not included in the list and they are most wanted in today technology. Ongoing globalization, the referred equipments becomes obsolete, as there are so many new and new instrument being used in R&D, which are not included in the list viz. HPLC System, Gas Chromatographic System etc. Therefore notification should be amended as "ANY INSTRUMENTS TO BE INSTALLED IN R&D WING BE DUTY FREE".
03	Still no decision has been taken against withdrawn of rebate of duty against NF 37/2007 dated 17.09.2007

(13) Other suggestion to be taken with various ministries (Attached) ANN-11

(14) Presentation of Member company on deletion of SION A-33. ANN-12