

PHARMACEUTICALS EXPORT PROMOTION COUNCIL

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

**POINTS FOR DISCUSSION WITH SHRI V K GUPTA, ADDITIONAL DGFT ON
4.02.2010, DGFT, NEW DELHI**

1. Revision / removal of CAP value of Ibuprofen:

Members have requested for revision / removal of CAP value for Ibuprofen is pending with DGFT, which may be considered.

2. Endorsements on DEPB Licenses:

Some of our members in Gujarat states that for DEPB license if issued from Vadodara Jt, DGFT office and export was from Mumbai sea/air port for use at Ahemdabad port then they are required to get RA from Mumbai and it costs a minimum of 10% of DEPB value. Since now every thing is on line, these unnecessary transaction costs may be reduced.

3. Claims under VKGUY / Focus Market/Focus Product schemes:

The chapter 3 of the FTP states that claims under VKGUY or FMS or FMP will be processed provided it is mentioned on the shipping bill and the words "WE WILL CLAIM EXPORT INCENTIVES UNDER CHAPTER 3 OF THE FTP" should appear on the shipping bill. Customs Authorities inform that they do not have any provision in their software and no code is allotted to mention the same and hence cannot be mentioned on the shipping bill.

4. Norms for Formulations:

Some of our members expressed that they are facing problems in exporting many formulations where input out norms are not fixed, where the API is used in potency/equivalent based. For example phenoxymethyl penicillin potassium tablets BP/USP, 250/500mg tablets. In this product the raw material is imported based on BOU and while formulation are based on mg to be added as 250mg tablet or 500 mg tablet. To make 250mg phenoxymethylpenicillin base about 285mg of phenoxymethylpenicillin potassium (salt form) per tablet to be added. But, advance licenses are issued on 250 mg basis only instead of 285 mg.

5. Plants and Plant Materials for manufacturing Phytochemicals for Export

As per schedule VII of Plant and Quarantine - Phytosanitary Certificate from supplying country is required (i.e. Country from where it is exported to India) should suffice. But Plant & Quarantine Officers at the ports are asking for original phytosanitary certificate from the original country of Origin. But parties

covering stocks from original country of origin are not ready to give phytosanitary certificate from Original Country of origin. This is affecting procurement of raw materials in India for manufacturing phytochemicals. DGFT may give necessary instructions to Plant & Quarantine to allow imports of plant materials by accepting Phytosanitary Certificate issued from country from where the item is last exported to India.

6. Penalty for losing EP copy:

If EP Copy is lost then DGFT is levying 1% penalty which is too harsh. In case if somebody loses it accidentally - then we should have an option to get another one duly attested by the customs.

7. Deemed exports:

In deemed exports - DGFT is asking for attestation by excise authorities on invoice as well as CT3 which excise authorities are not doing.

8. Redemption of licenses:

Redemption cases are getting delayed beyond their norms because lack of manpower.

9. Relaxation of Redemption Procedure:

DGFT should relax the redemption procedure for the unfulfilled Export Obligation due to lower yield than permitted under SION by allowing exporters to make payment of duty for the yield loss with relevant production data.

10. No clarity in case of bulk drug from unregistered source:

License issued under No Norms Para 4.71 of HBP. Subsequently lower Norms fixed by ALC by which time export and import are completed. When the import item is Restricted Product (bulk drug from Unregistered source), there is no clarity how to pay customs duty on excess import to regularize the License. Zonal DGFT should be able to regularize such cases but not taking any action to resolve the issue.

11. Amendments in the Shipping Bill:

License issued under No Norms Para 4.71 of HBP. Subsequently after date of export, as directed by ALC, description of export product amended in the License. The S/B obviously reflects name of export item as stated in the Original License, Customs refuse to make changes to the S/B at a later stage.

12. SIONs: Regularisation of License held up in cases where typographical error in published SION, as also where SION gives Chemical Name but import

documents mention Brand Name even though supplier's literature available to show both are same.

13. Companies which are into the manufacturing of few of the products for which the norms are not fixed and every time they need to wait for the details of the norms approved in the ALC meeting which is held at the DGFT office. They mention the consumption of norms in their license application as per their actual use but in most of the cases they find that the norms are being slashed to level of 50-60% of the actual and their purpose of exporting at a competitive price by using the advance license facility totally gets defeated.
14. Merchant Exporters are asked to furnish COA for every shipment which is a bit difficult for the exporters to obtain.
15. Additional export obligation.
16. Some of our members' shipping bills still not in online from the year 2007 port Vizag. For this they have contacted commissioner of customs they said there not having any data since it is old issues they advise to contact ICEGATE . Members are losing DEPB benefits.

Points discussed in the meeting taken by Shri Rajeev Kher, Joint Secretary on 12.01.2010:

1. 15% value addition for Advance Authorization scheme – Requested for restoring the earlier provision of 'positive value addition' instead of 15% value addition.
2. 98% yield for new drugs: While fulfilling Export Obligations for the Advance Authorizations taken by the exporters of pharmaceutical formulations, it insisted that there should be 98% yield. Exporters feel that 98% of yield is not possible for new drugs. Because of this condition, exporters are unable to fulfill the export obligation and they are considered as Defaulters
3. I/O norms for non-infringing process for patented products: Consumption of raw materials for products produced with non-infringing process for patented products would be more. Industry feels that such cases have to be differently considered and allow norms as per actual consumption.
4. Focus markets – Russia & Ukraine also to be included as most of the exports are to these countries.
5. Problems at ZDGFT, Mumbai: Exporters are facing many problems due to internal issues at ZDGFT, Mumbai. Exporters IEs are getting blocked and listed as defaulters. DGFT may call for data of such cases.

6. Re-import of returned material: While re-importing the returned material, exporters are asked to get the sample tested to establish the identity. This condition may be restricted to Drugs only and not for intermediates, as the laboratories do not established processes for testing intermediates, which is causing unnecessary delay in clearing the material by the exporters.
7. Extension / Revalidation of Export Obligation Period & Clubbing of Advance Licenses: Council is receiving number of requests for recommendation to consider extension / revalidation of export obligation period and also for Clubbing of Advance Licenses. In order to avoid delays in processing each individual cases, DGFT may consider giving one time relief to all the exporters.

IDMA Points:

1. Simplify permission to export "New Bulk Drugs"
2. Extension of Import License and export obligations as done earlier (two extensions of six months each)
3. Export Obligation Fulfilling 98% Yield on The Formulations.-Advance Authorisation -Currently, DGFT is insisting that there should be 98% yield on the formulations, and our exporters feel that for the new drugs it is not possible to get 98%, due to these reasons, all the exporters unable to fulfill the export obligation and they are considered as Defaulters. This is to be resolved immediately.
4. Enhancement In Wastage Norms Under SION: All the exporters of Tablets/Capsules ,Injections, IV Fusions, Syrups, Suspensions etc the wastage is low as the current FTP, it is affected by the fulfillment of the EO and added to the additional liabilities, we request to enhancement of the wastage norms under said SION which is pending more than 5 to 6 years.
5. Amendment of the Para 4.16 Ftp 2009-2014: In the recent policy announced a minimum 15% value addition criteria has been introduced on imported inputs under the Advance Authorization Scheme.This would severely impact the exports with the high import content products and some low value added dosage formulations, particularly API exports.
6. Raw materials imported from the China with the minimum value addition, it's not possible to have the said value addition. Even,in the case of DEPB the value addition in terms of imports and exports can be highly negative .DGFT have to consider the value addition to the minimum to import and exports to earn more foreign currency to India.
7. Enhacement of Normal Repatriation Period from 180 to 360days for The Staus Holders: Please note that this provision was available in earlier policy which is missing in the current policy. RBI continues with this policy and deleting this

which gives negative image of the DGFT also LAC. Due to the current status of the payment from the overseas crisis the longer credit period is essential for the export orders/marketing in the several new market areas.

8. Increase Import Validity Period To 36 Months: Due to the current transaction cost/freight for exports, we would request the DGFT to consider and allows period of EO up to three years and allowing validity of the License for imports also 36months which will help the exporters consistent of their the growth in exports.
9. Clubbing of DEPB With the Other Duty Credit Scrips under The Chapter 3 Of Ftp: At present the customs are not allowing clubbing the DEPB with the other scrips like FOCUS MARKET for debiting a single B/Entry due to the reasons these are two different notifications. The imports are costly and added cost to the products, the customs should allow to the current crisis.
10. DEPB for the Lotion and Creams to be inculcated: Currently lot of exports being made to new overseas markets and there is no DEPB for these products and the exporters are claiming only packing materials used instant of the products exported in huge quantity. Our request to the DGFT to add these products also in the DEPB list of the pharma immediately.

Association of Indian Medical Device Industry (AIMED) Points :

1. Country of Origin: In case of import of goods as a finished packed product, there should be mentioned country of origin on the product along with complete address of supplier and/or manufacturer. It will avoid any ambiguity of country of origin of the product or any misleading labeling and misrepresentation by importer for Indian tenders favouring Indian manufacturer, Indian origin goods. Customs may be directed to ensure compliance of the requirement at the import points.
2. Updation of shipping bills by custom authorities with DGFT: To avail export benefits – DEPB/FMS/FPS, it is required to submit online application on DGFT portal on the basis of updation of shipping bills by custom authorities. But shipping bills are not timely updated by custom authorities. In absence of updation of shipping bills, exporters are unable to submit application for DEPB/FMS/FPS. It is suggested to review the above and need to make timely online updation of shipping bills.
3. Market Assistance/Development Scheme: UK companies get more than 50% subsidy against their exhibition participation costs for overseas exhibitions for “Made in UK” products. For example if a UK company participates in the exhibition “MEDICA” at Germany, it is entitled to get this subsidy. While Indian Government promotes subsidy/ assistance to Indian companies for general fairs for diverse Indian products. Such support is not available, when Indian Medical

Companies participate in specialized exhibitions in Europe, UAE, South Africa and USA.

4. Free Sale Certificate: As per the latest guidelines in the EXIM Policy 2009—2014 regarding issuance of Free sale certificate, the guidelines & procedures are not being implemented in various regional offices of DGFT & as a result, exporters are facing tough time in getting required free sale certificate in time. We hereby suggest to give clear cut guidelines to all the regional offices for issuing free sale certificate to all the bonafide exporters without any hurdles.