

Exemption on materials for test kits

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Association of Diagnostic Manufacturers of India (ADMI) provides a platform for the Indian IVD manufacturers to voice their concerns and resolve issues. It has 27 members, which includes 21 manufacturers and six distributors and suppliers. It recommends

Exemption for antigens & antibodies in test kits

Under general exemption No. 122 (Notification No. 21/2002) at Sr. No. 83, which covers chapter 28, 29, 30 & 38, the following goods, namely life-saving drugs or medicines, including their salts and esters, bulk drugs used in the manufacturing of life saving drugs and diagnostic test kits are specified in List 4. For import of raw materials such as antigens or antibodies or any other ingredient corresponding to the manufacture of diagnostic test kits specified in List 4, benefit of duty exemption permitted for bulk drugs for manufacture of drugs or medicine is not extended since the words "diagnostic test kit" do not specify them. The import of raw materials such as antigens or antibodies or any other ingredient corresponding to the manufacture of diagnostic test kits specified in List 4, therefore, puts the local manufacturer at a disadvantage in comparison to those importing finished diagnostic test kits as diagnostic test kit is specified in List 4. The notification should, therefore, include the following: bulk drugs, antigens, antibodies (monoclonal/polyclonal), raw materials, components used in manufacture of life saving drugs, medicines including their salts and esters and diagnostic test kits.

The import of certain diagnostic kits were covered under exemption No. 122 Sr. No. 363 and is part of List 37. The following items, which were a part of the now abolished List 37, need to be included in List 4 to allow for a level playing field for both Indian manufacturers and importers.

Exemptions for ELISA kits components

Under the general exemption No. 122 at Sr. No. 95, various components for manufacturing ELISA kits have been allowed the benefit of lower duty. This list may be extended to include antigen or antibody on the solid phase for coating. The other key component is the enzyme conjugate and their stabilizing buffer and solutions. These key ingredients have not been covered by the current list, hence it needs to be enhanced and corrected to put the local ELISA kit manufacturer at par with the importer because all finished ELISA kits are imported at nil duty as per item No. 36 on List 4.

Specific suggestions on duty rationalization

With abolishing of List 37, all diagnostic devices are now covered under Chapter 90 (9027) customs unless they are part of General Exemption No.107, Sr.No.83, List 4. They, therefore, attract high duty rates, and it is recommended that they be classified under 9018 or nil duty to encourage access to newer technologies. Further, duty on manufacture or import of diagnostic reagents should be reduced to encourage manufacturing in India. The following need to be rationalized:

- Excise duty for manufacturing of diagnostics reagents may be made nil from existing 10 percent.
- Diagnostics reagents may be treated same as medical equipment under Sec 9018 from existing 26.75 percent
- Duty on PCR kits may be made nil from existing 26.75 percent as is the case for ELISA and CLIA diagnostics kits.
- All diagnostics equipment, including fully automated biochemical analyzers, may be assessed at nil duty or with a total duty of 9.63 percent as imposing of a duty of 14.72 percent will raise the cost of these hi-tech instruments significantly.
- Customs tariff for diagnostics kits may be based on criticality of the test rather than the technology.
- Second-hand laboratory and medical equipment should have a penal duty to disincentivize their import and sales in the country.

To encourage local manufacturers, I feel the following provisions may be given across the board, be it reagents, instrumentation, plastics and metal. Import duty should be there for all end products. CVD and excise may be exempted. Manufacturer should be able to import raw materials duty free.

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