

CONTRACT MANUFACTURING POLICY.

Drugs Registration Board recommended contract manufacturing policy in its 195th meeting. This was submitted to the Federal Government for concurrence, which was accordingly obtained. The implementation of this policy could not be started due to the panel inspection by the five members including one each from PPMA & Pharma Bureau. Due to long standing pendency of the new applications for the grant of contract permission and already granted permissions following amendments were approved by the Federal Minister for Health for the disposal of cases:-

- i. There should be special permission of 20 registrations for the firms, which are in building of their own sections, and the Chairman Registration Board may allow 20 products for contract manufacturing permission for registrations.
- ii. The panel inspections which are pre-requisite may be relaxed for one year and all the firms along with approval of all the pending applications may be granted for one year subject to panel inspections for further extensions. This will result in disposal of pendency along with facilitation of Pharma industry without any discrimination.

These amendments will lead to disposal of cases of contract manufacturing without panel inspection and one year permission will be granted. Within this period panel inspection will be conducted and further extension will be granted in the light of these inspection by five members panels, keeping in view the approved policy. Following additional conditions and clarifications may also be included into the policy:-

- a. The liability of the quality shall fall on the shoulders of contract manufacturers as provided under Section 32 of Drugs Act, 1976 for the Warrantors; however,

manufacturer may follow the specifications of the contract giver after validations.

- b. Both the contract giver and the contract acceptor shall retain 20s samples of each batch till the expiry of the product for reference.
- c. Contract manufacturer shall submit the detail of production of each batch of the contract manufactured drug to the area FID including the copy of supply order and invoice / warranty issued to the contract giver. He shall submit quarterly production and disposal reports on Form-7 to the Drugs Registration Board separately.
- d. The contract giver shall submit the sale record of each drug manufactured on contract basis to the area FID on monthly basis including the invoices of sales to the distributors.
- e. The area FID shall maintain the record of each firm for the products manufactured on contract basis and monthly report shall be submitted to the Registration Sections, where record shall be maintained for each firm.
- f. The procurement of raw material, packaging material and other relevant utilities shall be done by the contract manufacturers who shall maintain the records and stock registered. However, the contract manufacturer may nominate suppliers / vendors.
- g. Permission for contract manufacturing will be granted only for the drugs which required dedicated facilities / specialized technologies for local manufacturers.

However, drugs already being manufactured on contract basis could be entertained under existing policy.

- h. To encourage local manufacturing drugs registered in import will be allowed contract manufacturing without any restrictions.
- i. Likewise for export purpose all types of drugs will be allowed for contract manufacturing.
- j. Contravention to the any provision of this policy by the contract giver or contract acceptor shall lead to the cancellation of contracts by the Central Licensing & Registration Board.
- k. If any sample manufactured on contract basis is declared substandard / adulterated / spurious, the Registration Board shall immediately withdraw the contract permissions granted to the contract manufacturer, in addition to the proceedings as laid down in the law. The fate of the contract giver shall be decided according to his contribution and evidences.

Decision: The Central Licensing & Registration Board included the above mentioned proposals into the contract manufacturing policy. The final shape of the policy is as under:-

Contract manufacturing policy.

Pre-Requisites For Contract Manufacturing.

- i. Contract manufacturing will be allowed between two licensed manufacturers on the basis of human-to-human and veterinary-to-veterinary manufacturers. Contract manufacturing for psychotropic / narcotic drugs shall not be allowed.

- ii. On genuine need of Pharmaceutical units due to renovation of existing facilities or further improvements, for updating units suggested by regulatory authorities to meet the regulatory requirements for a specific / limited period for two and half years., maximally up to three years.
- iii. To utilize the surplus capacities of a pharmaceutical unit especially for the drugs which require self contained / dedicated facilities or specialized in nature and need specialist techniques or technologies.
- iv. Manufacturing units desirous of doing contract manufacturing should applied to the M/o. Health to obtain special license for this purpose, Specifying the dosage form(s), they intend to contract manufacture. Pre inspection will be conducted by a team of expert consisting of five (5) members three (3) from the Ministry and CL & RB and two (2) from the Pharma Industry having relevant expertise. The expenses of private members will be born by the applicant. Qualifying units will be allowed contract manufacturing and the certificate will be issued after approval from the CL & RB. These units will be permitted to conduct contract manufacturing. The above panels will also evaluate surplus capacities of the applicant for utilizations in contract manufacturing.
- v. Finally surplus capacity shall be defined by the Central Licensing and Registration Board after examination of report of panel of experts / panel of inspectors and number of already manufactured drugs for himself as well as by contract manufacturing. Surplus capacity will be equal to the installed capacity minus capacity utilized by the firm itself.
- vi. Contract manufacturing will also be encouraged for those important drugs which either remain short or produced in insufficient quantity to meet the public demand. M/o. Health may incorporate one or two drugs in the contract manufacturing list of any pharmaceutical unit, if it is required in public interest.
- vii. To encourage local production of imported drugs, importers will also be allowed for contract manufacturing from any local manufacturer having facilities to manufacture the drugs with the undertaking to establish their own manufacturing facilities within 2¹/₂ (two & half) years up to three 3 (three) years.
- viii. To encourage exports contract manufacturing permission will also be granted to the exporters from any local manufacturers having manufacturing facilities to manufacture those drugs. However, sale

of these drugs will not be permitted in the local market and in case violation contract manufacturing permission will be withdrawn.

- ix. The contract giving firm shall submit an undertaking of investment and creating its own manufacturing facilities within contract period.

B. Conditions for contract manufacturing.

- a. Contract giving unit can avail the facility for only 20 registered drugs while contract accepting unit will utilize his facility according to the surplus capacity defined by Central Licensing and Registration Board but not more than 10 contracts and number of products manufactured on contract basis shall not exceed from 50 per section.
- b. Both the contract giver and contract acceptor shall be liable for the contract manufactured drugs and both will submit a signed agreement according to the format approved by the Central Licensing and Registration Board.
- c. All the provisions of SRO 470(1)98, dated 15th May, 1998 (Schedule-H) and Rule 20(A) of Drugs (Licensing, Registering & Advertising) Rules, 1976 shall be applicable on contract manufacturing.
- d. This policy shall be applicable for a period of five(5) years i.e. up to 30th June, 2010. All firms availing of contract manufacturing facilities under this policy shall be liable to establish their own facilities up to this date. In case of failure to establish own facilities the contracts will be terminated after the expiry of said period.
- f. Both the contract giver and contract acceptor shall be manufacturing some registered products and the contract acceptors shall be manufacturing drugs for himself in particular section for which he has accepted the contract.
- g. Prices of all the similar generics manufactured on contract basis shall be same.
- h. All the firms already availing contract facility shall be treated on case to case basis subject to their previous performance and Chairman Central Licensing & Registration Board may extend their contracts up to 30th June, 2006 subject to the condition that he is satisfied about their performance / commitments.

- i. All the pending applications and new applications shall be processed according to contract manufacturing policy after final approval from the Government.
- j. Marketing of contract manufactured products through third parties / franchisers shall not be permissible. In case of proven violation contracts shall be liable to termination with immediate effect. The ethical promotion criteria laid down under schedule G of sub Rule 11 of Rule 30 of Drugs (Licensing Registering & Advertising) Rule 1976, shall be applicable on these drugs.
- k. The marketing authorization permission certificates will be issued only for the period of permission approved by the Board and its validity will be for that period.
 - l. The liability of the quality shall fall on the shoulders of contract manufacturers as provided under Section 32 of Drugs Act, 1976 for the Warrantors; however, manufacturer may follow the specifications of the contract giver after validations.
 - m. Both the contract giver and the contract acceptor shall retain 20s samples of each batch till the expiry of the product for reference.
 - n. Contract manufacturer shall submit the detail of production of each batch of the contract manufactured drug to the area FID including the copy of supply order and invoice / warranty issued to the contract giver. He shall submit quarterly production and disposal reports on Form-7 to the Drugs Registration Board separately.
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- p. The area FID shall maintain the record of each firm for the products manufactured on contract basis and monthly report shall be submitted to the Registration Sections, where record shall be maintained for each firm.
- q. The procurement of raw material, packaging material and other relevant utilities shall be done by the contract manufacturers who shall maintain the records and stock registered. However, the contract manufacturer may nominate suppliers / vendors.
- r. Permission for contract manufacturing will be granted only for the drugs which required dedicated facilities for local manufacturers. However, drugs already being manufactured on contract basis could be entertained under existing policy.
- s. To encourage local manufacturing drugs registered in import will be allowed for contract manufacturing.
- t. Likewise for export purpose all types of drugs will be allowed for contract manufacturing.
- u. Contravention to the any provision of this policy by the contract giver or contract acceptor shall lead to the cancellation of contracts by the Central Licensing & Registration Board.
- v. If any sample manufactured on contract basis is declared substandard / adulterated / spurious, the Registration Board shall immediately withdraw the contract permissions granted to the contract manufacturer, in addition to the proceedings as laid down in the law. The

fate of the contract giver shall be decided according to his contribution and evidences.

Drugs Registration Board decided the pending applications in the light of revision made by the Federal Government.