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DCGI office not empowered to issue CoPP under D&C Act, TNDCOA

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The Tamil Nadu Drug Control Officers Association (TNDCOA), which in October last year had challenged the DCGI order relating to centralisation of CoPP in Madras High Court, has contended in the court that the DCGI office (CDSCO) has the power to grant licences to only three items such as blood & blood products, intravenous fluids and sera & vaccine.

In its reply affidavit to the Madras High Court, which is hearing the CoPP case, the TNDCOA said that as per the amendment in the Drugs & Cosmetics Acts & Rules in 1992, the CDSCO has the power to grant licences only for three items such as blood & blood products, intravenous fluids and sera & vaccine.

However, in the year 2005, 10 medical devices have also been included under Rule 68 (A) of the Act. The CDSCO stands as approving authority only for these few items of drugs as defined under Rule 68 (A), the affidavit said. The association in its reply affidavit clarifies that the issuance of CoPP under WHO certification scheme is not a statutory function governed by Drugs & Cosmetics Act of 1940 and Rules of 1945.

But it has informed the court that the state drug controlling authorities, being licensing authorities as per the law, are competent to issue the CoPP and they alone can satisfy the requirements of WHO regulations.

According to them, the state drug controlling authorities are the competent persons to be certifying authority under WHO certification scheme as per the requisite criteria stated therein considering the provisions of D&C Act and rules. Under the provisions of the Act, the state drug controlling authorities have been notified as licensing authorities to grant or renew license for manufacture or sale or distribution of drugs.

The reply affidavit says that the statement in the counter Affidavit filed by the CDSCO Chennai office that the WHO empowers only National Regulatory Authority of a country as the competent authority to issue CoPP, is incorrect and misleading. It also said there are separate definitions in the WHO guidelines on ‘Competent authority’ and ‘Certifying authority’. The affidavit says that the claims of CDSCO as it is the National Regulatory Authority is factually incorrect because there is no such NRA constituted under the Act.

In the year 1977, the Ministry of Health and Family Welfare of the Government of India decided that India should participate in the Certification Scheme of the quality of Pharmaceutical products moving in international commerce and accordingly the WHO was informed. Considering the fact that the state governments are responsible for issuing licences to drug manufacturers and for ensuring that the manufacturers adhere to the prescribed standards, the WHO was informed that drug controllers in the various states in India would be the competent authority to issue necessary certificate for pharmaceutical products

manufactured in their respective states and which are exported out of India.

Further it said that the DCGI was usurping the powers vested with the state drug controlling officers by attempting to centralize the WHO GMP Certification and his decision was illegal. They also alleged that the minutes of the Drugs Consultative Committee (DCC) held in 1995 and in 1998 were not correctly reported in the counter affidavit filed by the counter petitioner. In the DCC meetings, the views expressed by state drug controllers were recorded and accordingly it was left to the state licensing authorities to issue the certificates.

Meanwhile, the case of issuance of CoPP is still continuing in the Madras High Court for a final verdict and it will come up again for hearing on February 1.