Karnataka High Court
Karnataka Drugs And ... vs Central Durgs Standard Control ... on 4 December, 2015
Author: Anand Byrareddy

1

IN THE HIGH COURT OF KARNATAKA AT BENGALURU

DATED THIS THE 04TH DAY OF DECEMBER 2015

BEFORE:

THE HON'BLE MR. JUSTICE ANAND BYRAREDDY

WRIT PETITION No.30513 OF 2009 (GM-RES)

BETWEEN:

Karnataka Drugs and
Pharmaceuticals Manufacturers
Association, 3B,
Bharath Deluxe Apartment,
44/1, A and B, Fairfield Layout,
Race Course Road,
Bangalore 560 001.
Represented by its Secretary,
Mr. Jatish Sheth.
...PETITIONER

(By Shri Rajendra M.S., Advocate for M/s. Holla and Holla)

AND:

1. Central Drugs Standard
Control Organisation,
Directorate General of Health
Services, Ministry of Health and
Family Welfare,
Food and Drugs Administration Bhawan,
Kotla Road,
New Delhi 110 002.

2

2. Drugs Controller for
The State of Karnataka,
Drugs Control Department,
Next to Carlton House,
Palace Road,
Bangalore 560 001.

...RESPONDENTS

(By Smt. M. Birdy Aiyappa, Advocate for Respondent No.1;
Smt. Pramodhini Kishan, Government Pleader for Respondent
No.2)

*****

This Writ Petition filed under Articles 226 and 227 of the Constitution of India, praying to declare that the first respondent , is not the competent authority to certify products which are meant for export under the who scheme and quash the order of the first respondent dated 1.9.2009 vide Annexure-C.

This petition having been heard and reserved on 4.11.2015 and coming on for pronouncement of orders this day, the Court delivered the following:-

ORDER

Heard the learned Counsel for the petitioner and the learned Counsel for the respondents.

2. The facts of the case are as follows:

The petitioner is said to represent the pharmaceutical industry in the State of Karnataka. It has been formed with the object of protecting the interest of the manufacturers of pharmaceuticals in the State.

It is contended that in India, the regulation of the licensing requirements and other matters in respect of import, manufacture, distribution and sale of drugs are governed by the Drugs and Cosmetics Act, 1940 (Hereinafter referred to as the 'DC Act', for brevity) and the Drugs and Cosmetics Rules, 1945. (Hereinafter referred to as the 'DC Rules' for brevity). The said Act and Rules only provide for the import, manufacture, distribution and sale of drugs. There are no provisions regarding the licensing requirement for the export of drugs.

A manufacturer, who has obtained a license to manufacture a drug as contemplated under Chapter IV of the DC Act, is entitled to export the drugs after fulfilling the requirements of the importing country, in terms of quality parameters, labelling, registration requirements and documentation. As different countries have different regulatory procedures, the World Health Organization (WHO) has framed a Scheme for product certification in matters pertaining to import of drugs by the countries who are signatories to the said Scheme. The certification protocol is called 'Certificate of Pharmaceutical Product' (COPP).

The Scheme aforesaid envisages the certification of the license status of the manufacturer, the particulars of the drug and that the manufacturer has complied with the 'Good Manufacturing Practices', and that the manufacturing unit is subject to periodic inspection.

It is said that WHO has issued guidelines for the implementation of the Scheme. According to the same, a list of competent authorities of countries participating in the WHO Certification Scheme on

the quality of pharmaceutical products marketed internationally are specified. As regards India, in respect of each state, the respective State Drug Controller is nominated as the competent authority for the purposes of the product certification. The second respondent herein was considered the Competent Authority for product certification under the Scheme. And since the year 1994, the second respondent is said to be exercising the power in that regard.

It is said that during the year 2008, products worth about Rs.1536 crore were exported from Karnataka, which was about 5% of the entire country's export of drugs. The second respondent had levied a 'user fee charge' on such exports. On an average, the second respondent issues over 25000 certificates annually and it would translate to a revenue of over Rs.1 crore, annually.

It however, transpires that the first respondent abruptly chose to take over the functions of the second respondent in the year 2009. This, it is said, is in complete contravention of the Guidelines issued by the WHO. It is the grievance of the petitioner that this move on the part of the first respondent causes severe hardship to the drug manufacturers. It has created an avoidable duplication of the process of inspection and control. It is stated that in the matter of export of drugs, time schedules are to be strictly adhered to. Any delays run the risk of the concerned manufacturer being blacklisted. Every drug exported requires to be separately certified. There are said to be over 3400 products exported from Karnataka, to over 75 countries. In view of the centralization of the certification process on an all India basis, delay is inevitable and in the result, the market is destroyed. The effect on the industry and the people who depend on it for their livelihood is devastating. The State exchequer also stands to lose revenue.

It is in this background that the writ petition is filed.

3. It is asserted that the WHO guidelines indicate that the State Drug Controllers are alone competent to certify each product sought to be exported under the WHO Scheme.

It is urged that the first respondent had no power to issue the impugned notification and that it does not indicate the reasons for such action. The said change imposes a cumbersome duplication of procedure causing serious delays and hardship to manufacturers exporting their pharmaceutical products.

4. The first respondent has contested the petition and it is stated that the petition proceeds on an incorrect and misleading premise. It is emphasized that the WHO has recognized only the Drugs Controller General of India as the Competent Authority with respect to issuance of COPP. It is asserted that since the year 1995, as decided at the Drugs Consultative Committee meeting, a statutory body under the DC Act held on 24.2.1995, where all the State Drug Controllers, as members were present, there was to be only one authority, namely, DCGI to issue the COPP for the pharmaceutical products exported. It is a voluntary function of the National Regulatory Authority to implement the WHO Scheme in India, to ensure that the quality of the products conforms to international standards. The provisions of the Act and Rules do not prescribe that the Second respondent issue the COPP. And again at a meeting of the DCC on 17.3.1998, it was agreed that till such time the issuance of certificates at the national level commences by the National Regulatory

Authority, the State Drug Control Authorities would process the pending applications. This measure was warranted as it had been noticed by WHO that there was variance in issuance of COPP on account different interpretations of the guidelines by the State Drug Controllers of different states.

The contention that there would be a duplication of the process of inspection and certification or that there would be an inordinate delay, it is contended, is also an imagined apprehension. It is stated that the first respondent has established zonal and sub-zonal offices through out the country, which offices would be competent to issue the certification on behalf of the first respondent. It is claimed that with state of the art facilities now available to the first respondent, it is contended , that there is need be no concern of any delay and hardship to the manufacturers.

5. In the light of the above contentions, it is to be noticed from the material produced on record that the sequence of events is borne out from a perusal of the same. As for instance, the initial transition of the regime in the first respondent assuming exclusive authority to issue the COPP and the difficulties faced during the transitory period is evident from the following letter issued to the second respondent by the first respondent.

> "CENTRAL DRUGS STANDARD CONTROL ORGANISATION D.G.H.S., Min. of Health & Family Welfare, Government of India Camp at Chennai No.50-4/Gen/SZ/2007-618 Dated 30th April 2007 Dr. B.Sripathi Rao Drugs Controller I/c, Karnataka: Bangalore Sir As you are aware the WHOGMP Certification inspections are to be carried out as per the guidelines laid down in the DCC. The procedures indicate that an applicant seeking WHOGMP Certificate has to make an application induplicate, forward one to concerned zonal office and the other to concerned state. The zonal officers based on the number of applicants received finalises the programme of inspections and the states depute their officers so that joint inspection is carried out by the Central and State Drugs Inspectors together and also based on the need have an expert in the inspection team like cases of vaccines etc. The responsibility of writing the report is with the Central drugs Inspector and sallent observations are recorded in the standardized check list prepared for the purpose.

Based on the recommendations of the inspection team, the State Drugs Controller, issues the COPP to the applicant with an intimation to the zonal office. The validity of the GMP certification is restricted initially to be granted for 2 years. Under special circumstances it can be extended for one more year.

In case of application for COPP for additional products, the applicant shall apply to zonal office with requisite information like stability date, validation report etc. which shall be by the zonal office and if satisfied, recommendations are forwarded by the zonal officer to issue COPP for additional products with the condition that the validity shall get restricted based on the inspection. However if the state/zonal officer considers the inspection is warranted to consider for additional products, he shall carry out the joint inspection.

I have been informed by the Deputy Drugs Controller (India) south Zone that for the last 16 months your office is carrying out WHO,GMP inspections and granting COPP independently. This is against the procedures laid down and also the understanding the GOVERNMENT OF INDIA given to World Health Organization.

I shall appreciate if you can look into the matter and ensure that the procedures laid down in DCC are followed in case of WHO-GMP Certification. If there are any specific problems of delay and non co-operation by the zonal office, you are at liberty to write to me so that we can find a solution in the matter.

Yours faithfully, Sd/-

(Dr. M. Venkateswarlu) DRUGS CONTROLLER GENERAL (INDIA)"

And the fact that the first respondent had achieved the object of ensuring that the Guidelines issued by the WHO were being adhered to is evident from the congratulatory letter to the first respondent from the WHO, which is as follows:-

> "Tel.direct: +41 22791 4050/3904 Dr.Surinder Singh Fax direct:+41227914971 Drugs Controller E-mail: Woodd @who.int General (India) In reply please Ministry of Health and Refer to: 18-370-42SEAR Family Welfare, QSS/LB-lkb FDA Bhawan Kotla Road, Near Bal Bhavan, New Delhi110 002 India.
>
> Your reference:
>
> Dear Dr Singh, I would like to thank you for the active support that you have provided to assist WHO by conducting a parallel review, with Health Canada, of the Meningococcal A vaccine that is of great importance to combat the yearly meningitis epidemic that affects children in approximately 25 countries in Africa.
>
> We are also very satisfied to note that most of the WHO recommendations that were issued in April 2009, following the NRA assessment, have been very closely followed up. We take particular note that some new regulations have been enforced such as:
>
> 1. Use of an adapted ICH Common Technical Dossier (CTD) based on the Canadian experience, to submit vaccine applications for marketing authorization.

2. In depth vaccine evaluations for marketing authorization and clinical trials, tested with the JE and Meningococcal applications submitted in April and June 2009.

3. Issuing of "Certificate of Pharmaceutical Product approvals" (COPP) performed by the Central Drugs Standard Control Organization (CDSCO) only, whereas in the past it was decentralized.

4. Establishment of a quality management system team, with about 15 staff dedicated only to vaccines and biologicals, and an additional 30 staff expected in CDL Kasauli.

5. Updated web site with online feedback on decisions by DCG(I) office.

6. Continuous GMP enforcement in all vaccines facilities as per international recognized standards of GMP.

We appreciate the steps taken by the National Regulatory Authority of India to implement the above recommendations from WHO. The above decisions will help DCG(I) to comply with globally recognized international standards, particularly points 3 and 6, that we believe are critical to the quality of products being exported out of India.

cc: WR, India Dr P.Francis, WR Office India Dr A. Thapa, SEARO, Coordinator, IVD Dr A. Chawla, SEARO/IVD/VSQ Mr S.Guichard, SEARO/Thailand Mr L.Belgharbi, HQ/IVB/QSS Dr N. Dellepiane, HQ/IVB/QSS Dr S. Singh, New Delhi I8-370-42SEAR As you know we are closely following the implementation of all WHO NRA recommendations and will continue to provide support for the NRA Institutional Development Plan (IDP) as agreed. We would like to inform you that the next visit of Mr. Lahouari Belgharbi is scheduled on 28 October 2009 and we shall be grateful if you would arrange for an update of the NRA IDP with the whole vaccine team between 1 pm and 5 pm in your office. In addition to the above, we assure you that we will provide you with our technical support in the implementation of the IDP for the NRA of India. Thank you for your continued cooperation.

Your sincerely, Sd/-

(Dr. David Wood) Coordinator Quality, Safety and Standards"

In the above circumstances, it cannot be said that the grounds urged in the petition or the apprehensions expressed - merit consideration. Consequently, the petition is dismissed.

Sd/-

JUDGE nv*