



2024:DHC:4952



* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

Date of decision: 02nd JULY, 2024

IN THE MATTER OF:

+ **W.P.(C) 6292/2022 & CM APPL. 18956/2022**

COLOPLAST INDIA PRIVATE LIMITED Petitioner

Through: Mr. R. Jawahar Lal, Mr. Siddharth
Bawa and Mr. Anuj Garg, Advocates.

versus

UNION OF INDIA AND ANR. Respondents

Through: Mr. Anurag Ahluwalia, CGSC with
Ms. Avshreya Pratap Rudy, Advocate
for R-1 and 2.

CORAM:
HON'BLE MR. JUSTICE SUBRAMONIUM PRASAD

JUDGMENT

1. Petitioner has approached this Court seeking a direction to the Respondents to declare that Surgical Bandages/Dressings do not fall within the scope of regulation monitoring under Para 20 of the Drug Price Control Order, 2013 (*hereinafter referred to as 'the DPCO'*). The Petitioner also seeks for quashing of Demand Notice No. F. No. 20(8)/16/2018/Div.III/OC/NPPA dated 11.03.2022 issued by Respondent No. 1 on the ground that it is without jurisdiction vested under Para 20 of the DPCO, 2013.

2. The facts, in brief, as stated in the Writ Petition, reveals that the Petitioner is a company incorporated under the Companies Act and is an affiliate of Coloplast Group, a Denmark-based multinational and a market



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leader in Wound and Skin Care products including specialized Surgical Dressings. It is stated that on 08.01.2018, a Show Cause Notice was issued by the NPPA to the Petitioner stating that the Petitioner has violated Para 20 of the DPCO by increasing the MRP for the eight categories/variants of Surgical Dressings by 12% to 43% during the year 2016 in comparison to the preceding year i.e., 2015. Vide the said Show Cause Notice the NPPA had further directed the Petitioner to furnish the batch-wise production/import and sales details of the eight variants of the surgical dressings with corresponding MRP for the years 2014-15, 2015-16, 2016-17, and 2017-18 duly certified by a Chartered/Cost and Management Accountant to see as to whether the Petitioner has acted contrary to Clause 20 of DPCO.

3. It is the contention of the Petitioner that the surgical dressings are not covered within the ambit of DPCO. The short issue which arises for consideration is as to whether the NPPA has the jurisdiction to issue a Show Cause Notice to the Petitioner herein for surgical dressings on the ground that the surgical dressings are covered under Para 20 of the DPCO or not.

4. At this juncture, it is apposite to reproduce paragraph No.20 of the DPCO and the same reads as under:

“20. Monitoring the prices of non-scheduled formulations.

(1) The Government shall monitor the maximum retail prices (MRP) of all the drugs, including the non-scheduled formulations and ensure that no manufacturer increases the maximum retail price of a drug more than ten percent of maximum retail price during preceding twelve months and where the increase is beyond ten



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percent of maximum retail price, it shall reduce the same to the level of ten percent of maximum retail price for next twelve months.

(2) The manufacturer shall be liable to deposit the overcharged amount along with interest thereon from the date of increase in price in addition to the penalty.”

5. A perusal of paragraph No.20 of the DPCO indicates that the Government has the power to monitor the MRP of all the drugs, including the non-scheduled formulations and ensure that no manufacturer increases the MRP of a drug more than ten percent of maximum retail price during preceding twelve months. The issue as to whether surgical dressings would be covered under the definition of drugs or not came up for consideration before the Apex Court in Chimanlal Jagjivan Das Sheth v. State of Maharashtra, **AIR 1963 SC 665**, wherein the Apex Court held that surgical dressings would come under the purview of drugs.

6. Material on record indicates that on 20.04.2010 the Ministry of Health and Family Welfare, Government of India, notified about 14 medical devices, including surgical dressings, to be considered as drugs under Section 3(b)(iv) of the Drugs & Cosmetics Act, 1940 (*hereinafter referred to as 'the D&C Act'*). It is stated that on 31.10.2012 a guidance note was issued by the Central Drugs Standard Control Organization (*hereinafter referred to as 'the CDSCO'*) wherein surgical dressings have been referred to as products which are regulated as Drugs under the D&C Act.

7. It is the contention of the learned Counsel for the Petitioner that on 09.07.2014 the CDSCO issued an Order listing medical devices which have been notified and in that Order "Surgical Dressing" is not listed as a medical



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device notified as a 'drug' and the reference to "regulation" of Surgical Dressing under the D&C Act has been removed. He further submits that vide Notice dated 29.06.2017 the CDSCO clarified that only 14 devices mentioned in the Schedule alone would be included in the definition of drugs under Section 3(b)(iv) of the D&C Act and any device other than those 14 devices do not require regulation. Learned Counsel for the Petitioner, therefore, submits that in view of the clarification issued by the CDSCO, surgical dressings cannot be included under the definition of drugs. It is stated by the learned Counsel for the Petitioner that vide notification dated 31.03.2020, issued by the NPPA it was notified that Medical Devices intended for use in human beings or animals have been notified as Drugs with effect from 01.04.2020 and all medical devices shall accordingly be governed under the provisions of the DPCO. He, therefore, states that the Show Cause Notice issued to the Petitioner is prior to 01.04.2020 and is beyond the jurisdiction of the NPPA as the surgical bandages are not covered under the DPCO.

8. *Per contra*, learned Counsel for the Respondent contends that the surgical dressings come under the purview of drugs and there is no dispute on this because of the Judgment of the Apex Court in Chimanlal Jagjivan Das Sheth (supra). He further states that surgical devices are regulated as drugs under the DPCO and they have always been regulated as drugs. He places reliance on OM Dated 12.05.2017, issued by the NPPA, wherein surgical dressings have been included in drugs for monitoring the price movement and, therefore, surgical dressings are covered under the paragraph No.20 of the DPCO. Learned Counsel for the Respondent states that the



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notification dated 09.07.2014 cannot be relied on for the reason that the Judgment of the Apex Court in Chimanlal Jagjivan Das Sheth (supra) has always read surgical dressings as drugs. Learned Counsel for the Respondent also places reliance on Rules 69, 69A, 75, 75A and 76 read with Schedule M-III of the Drugs and Cosmetics Rules, 1945 to contend that surgical dressings are regulated as drugs.

9. Heard the Counsels for the parties and perused the material on record.

10. Paragraph No.20 of the DPCO gives power to the Government to monitor the MRP of all the drugs, including the non-scheduled formulations and ensure that no manufacturer increases the MRP of a drug more than ten percent of maximum retail price during preceding twelve months.

11. Section 3(b) of the D&C Act defines Drugs and the same reads as under:

“(b) "drug" includes—

(i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;

(ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;

(iii) all substances intended for use as components of a drug including empty gelatin capsules; and



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(iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board;”

12. A perusal of Section 3(b)(iv) of the D&C Act shows that all devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings are included as Drugs.

13. The Apex Court in Chimanlal Jagjivan Das Sheth (supra) while interpreting Section 3(b)(iv) of the D&C Act has observed as under:

“3. Though an attempt was made to argue that the said articles were had been proved to be below the prescribed standard, it was subsequently given up. The only question that was argued is whether the said articles are drugs within the meaning of Section 3(b) of the Act. The said section reads:

“‘drug’ includes:

(i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the treatment, mitigation or prevention of disease in human beings or animals other than medicines and substances exclusively used or prepared for use in accordance with the Ayurvedic or Unani systems of medicine, and

(ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermins or insects which cause disease in human



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beings on animals as may be specified from time to time by the Central Government by notification in the Official Gazette.”

The said definition of “drugs” is comprehensive enough to take in not only medicines but also substances intended to be used for or in the treatment of diseases of human beings or animals. This artificial definition introduces a distinction between medicines and substances which are not medicines strictly so-called. The expression “substances”, therefore, must be something other than medicines but which are used for treatment. The part of the definition which is material for the present case is “substances intended to be used for or in the treatment”. The appropriate meaning of the expression “substances” in the section is “things”. It cannot be disputed, and indeed it is not disputed, that absorbent cotton wool, roller bandages and gauze are “substances” within the meaning of the said expression. If so, the next question is whether they are used for or in “treatment”. The said articles are sterilized or otherwise treated to make them disinfectant and then used for surgical dressing; they are essential materials for treatment in surgical cases. Besides being aseptic these articles have to possess those qualities which are utilized in the treatment of diseases. Thus for instance, in the case of guaze-one of the articles concerned in this appeal — it has to conform to a standard of absorbency in order that it might serve its purpose : otherwise the fluid which oozes is left to accumulate at the site of the wound or sore. The legislature designedly extended the definition of “drug” so as to take in substances which are necessary aids for treating surgical or other cases. The main object of the Act is to prevent sub-standards in drugs, presumably for maintaining high standards of medical treatment. That would certainly be defeated if the necessary concomitants of medical or surgical



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treatment were allowed to be diluted : the very same evil which the Act intends to eradicate would continue to subsist. Learned Counsel submitted that surgical instrument would not fall within the definition and that guaze and lint would fall within the same class. It is not necessary for the purpose of this appeal to define exhaustively “the substances” falling within the definition of “drugs”; and we consider that whether or not surgical instruments are “drugs”, the articles concerned in this case are. Learned counsel for the appellant sought to rely upon a report of a high powered committee consisting of expert doctors, who expressed the opinion in the report that as the surgical dressings did not come under the purview of the Drugs Act, no control on their quality was being exercised. Obviously, the opinion of the medical experts would not help us in the construing a statutory provision. We, therefore, hold, agreeing with the High Court, that the said articles are substances used for or in the “treatment” within the meaning of Section 3(b) of the Act.”

14. A perusal of the abovementioned paragraph shows that the Apex Court has held that absorbent cotton wool, roller bandages and gauze are *substances* within the meaning of drugs.

15. On 20.04.2010 Government of India issue a notification and the same reads as under:



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LIST OF NOTIFIED MEDICAL DEVICES

The Ministry of Health and Family Welfare, Govt. of India under following Gazette notifications has notified the following devices to be considered as drugs under Section 3, Clause (b) . Sub clause (iv) of the Drugs and Cosmetics Act: -

S.No	Name of the device	Notification Number	Date of notification
1	Disposable Hypodermic Syringes	GSR 365 (E)	17-03-1989
2	Disposable Hypodermic Needles	GSR 365 (E)	17-03-1989
3	Disposable Perfusion Sets	GSR 365 (E)	17-03-1989
4	In vitro Diagnostic Devices for HIV, HBsAg and HCV	GSR 601(E)	27-08-2002
5	Cardiac Stents	S.O. 1468 (E)	06-10-2005
6	Drug Eluting Stents	S.O. 1468 (E)	06-10-2005
7	Catheters	S.O. 1468 (E)	06-10-2005
8	Intra Ocular Lenses	S.O. 1468 (E)	06-10-2005
9	I.V. Cannulae	S.O. 1468 (E)	06-10-2005
10	Bone Cements	S.O. 1468 (E)	06-10-2005
11	Heart Valves	S.O. 1468 (E)	06-10-2005
12	Scalp Vein Set	S.O. 1468 (E)	06-10-2005
13	Orthopaedic Implants	S.O. 1468 (E)	06-10-2005
14	Internal Prosthetic Replacements	S.O. 1468 (E)	06-10-2005

Note: Further, the following products are regulated as 'Drugs' under Drugs & Cosmetics Act & Rules there under: -

1. Blood Grouping Sera
2. Skin Ligatures, Sutures and Staplers
3. Intra Uterine Devices (Cu-T)
4. Condoms
5. Tubal Rings
6. Surgical Dressings
7. Umbilical Tapes
8. Blood/Blood Component Bags

16. A perusal of the said notification indicates that surgical dressings were always regulated under the D&C Act.

17. Notification dated 09.07.2014, issued by the CDSCO, reads as under:



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29/Misc./5/2014-DC
Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
(Medical Device and Diagnostic Division)

Food & Drugs Administration Bhawan,
Kotla Road, New Delhi-110002

Date: 09.07.2014

Office Order

Sub: Clarification for regulation of medical devices under the provision of Drugs and Cosmetics Act and Rules thereunder- regarding

The following categories of medical devices were notified by the Ministry of Health and Family Welfare through Gazette notification mentioned hereunder to be considered as Drug under Section 3 clause (b), sub clause (iv) of the Drugs and Cosmetics Act, 1940:-

S. No.	Name of the Device	Notification Number	Date of notification
1.	Disposable Hypodermic Syringes	GSR 365 (E)	17.03.1989
2.	Disposable Hypodermic Needles	GSR 365 (E)	17.03.1989
3.	Disposable Perfusion Sets	GSR 365 (E)	17.03.1989
4.	In Vitro Diagnostic Devices for HIV, HBsAg and HCV	GSR 601 (E)	27.08.2002
5.	Cardiac Stents	S.O. 1468 (E)	06.10.2005
6.	Drug Eluting Stents	S.O. 1468 (E)	06.10.2005
7.	Catheters	S.O. 1468 (E)	06.10.2005
8.	Intra Ocular Lenses	S.O. 1468 (E)	06.10.2005
9.	I.V. Cannulae	S.O. 1468 (E)	06.10.2005
10.	Bone Cements	S.O. 1468 (E)	06.10.2005
11.	Heart Valves	S.O. 1468 (E)	06.10.2005
12.	Scalp Vein Set	S.O. 1468 (E)	06.10.2005
13.	Orthopaedic Implants	S.O. 1468 (E)	06.10.2005
14.	Internal Prosthetic Replacements	S.O. 1468 (E)	06.10.2005

It is hereby clarified that any devices other than above do not require any registration, licence, permission or NOC for their import or manufacture, sale and distribution so far as the provisions of the Drugs and Cosmetics Act and Rules made thereunder are concerned.


(Dr. G. N. Singh)
Drugs Controller General (I)

To

1. All State Drugs Controller
2. Zonal / Sub-Zonal/Port officers of CDSCO.

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18. The argument of the learned Counsel for the Petitioner that since only 14 medical devices have been sought to be regulated under the D&C Act and, therefore, surgical dressings are outside the ambit of the D&C Act, cannot be accepted for the reason that a perusal of the notification dated 20.04.2010 shows that all the 14 medical devices mentioned in the said notification were always treated as drugs under the D&C Act. The fact that surgical dressings is not covered in the 14 items mentioned in the notification dated 09.07.2014 does not mean that it is not covered under the meaning of drugs under the D&C Act. The Apex Court in Chimanlal Jagjivan Das Sheth (supra) has held that Surgical Dressings would come within the purview of drugs and the same is binding on this Court under Article 141 of the Constitution of India.

19. Article 144 of the Constitution of India mandates that all the authorities have to work in aid of the Apex Court and, therefore, the law laid down by the Apex Court insofar as absorbent cotton wool, roller bandages and gauze, including surgical dressings, would always be deemed to be covered under the definition of drugs and, therefore, would be covered under paragraph No.20 of the DPCO. The argument of the learned Counsel for the Petitioner that the notification dated 31.03.2020 would only be prospective and, therefore, the Show Cause Notice issued to the Petitioner be set aside, cannot be accepted because the notification dated 31.03.2020 is only clarificatory in nature and surgical dressings have always been covered under the definition of Drugs under the D&C Act by virtue of the judgment of the Apex Court in Chimanlal Jagjivan Das Sheth (supra).



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20. In view of the above, this Court does not find it expedient to interfere with both the Show Cause Notice and the Demand Notice issued against the Petitioner.

21. Accordingly, the Writ Petition is dismissed along with the pending applications, if any.

22. It is made clear that the mode of calculation of charges would be as per the Judgment of this Court in Union of India and Another v. Bharat Serums and Vaccines Limited, 2023 SCC OnLine Del 7262.

SUBRAMONIUM PRASAD, J

JULY 02, 2024

Rahul