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

Judgement reserved on 27.02.2023

% *Judgement pronounced on 01.09.2023*

\+ **W.P.(C) 10514/2019, CM Nos.43497/2019, 50395/2019, 29106/2020, 9412/2021 & 15630/2021**

THE SURGICAL MANUFACTURERS & TRADERS ASSOCIATION THROUGH ITS AUTHORISED REPRESENTATIVE ..... Petitioner

Through: Mr Adit S. Pujari, Mr Maitreya Subramaniam, and Ms Kajal Dalal, Advocates.

versus

UNION OF INDIA ..... Respondent

Through: Mr Kirtiman Singh, CGSC, with Ms Shreya V. Mehra and Ms Durgesh Nandini, Advocates.

\+ **W.P.(C) 10478/2020, CM Nos.33135/2020 & 33678/2021**

SURGICAL MANUFACTURERS AND TRADERS ASSOCIATION ..... Petitioner

Through: Mr Adit S. Pujari, Mr Maitreya Subramaniam, and Ms Kajal Dalal, Advocates.

versus

UNION OF INDIA ..... Respondent

Through: Mr Vikram Jetly, CGSC with Ms Shreya Jetly, Advocate.

CORAM:
HON'BLE MR JUSTICE RAJIV SHAKDHER
HON'BLE MS JUSTICE TARA VITASTA GANJU

RAJIV SHAKDHER, J.:

Prefatory Facts:

1. These are two writ petitions filed by the Surgical Manufacturers and Traders Association [hereafter referred to as "the Association"] to assail, among other things, two notifications.

1.1. The first writ petition, i.e., WP (C) 10514/2019 [hereafter referred to as "2019 writ petition"], lays a challenge to the Notification dated 03.12.2018 [hereafter referred to as "2018 Notification"]. In addition to it, challenge is also laid to Section 3(b)(iv) and Section 5(2) of the Drugs and Cosmetics Act, 1940 [hereafter referred to as the "1940 Act"].

1.2. Insofar as WP (C)10478/2020 [hereafter referred to as "2020 writ petition"] is concerned, it seeks to assail the Notification dated 11.02.2020 bearing no. SO 648(E) [hereafter referred to as "1st 2020 Notification"]. These notifications will be collectively referred to as "the impugned notifications" unless the context requires otherwise.

2. Both notifications have been issued by the Central Government via the Ministry of Health and Family Welfare [hereafter referred to as "MHFW"]. Significantly, both notifications deal with medical devices. The 2018 Notification brought four medical devices within the ambit of "drug" as defined under Section 3(b)(iv) of the 1940 Act. The 1st 2020 Notification has spread the net to cover all medical devices to the consternation of the Association.

3. The Association claims to be a registered society representing over 400 members, spread all over India, who are in the business of manufacturing and trading in surgical, medical, hospital, and healthcare equipment and

supplies both within India and those imported into the country.

4. The 1940 Act was amended via the Amendment Act 68 of 1982, with effect from 01.02.1983, which led to the inclusion of medical devices in the definition of "drug" medical devices as well, by insertion of sub-clause (iv) in Section 3(b) of the 1940 Act. After the amendment, Section 3(b) reads as follows:

> ***"3. Definitions**.—In this Act, unless there is anything repugnant in the subject or context,*
> ***xxx.** **xxx** **xxx***
> *(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 [the]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*
> ***(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**...*"*
>
> [Emphasis is ours]

5. It is also common ground that since the time Section 3(b) of the 1940 Act was amended, and medical devices were brought within the sway of the expression "drug", MHFW has issued several Notifications bringing various medical devices under the definition of "drug". These Notifications are dated 17.03.1989, 27.08.2002, 06.10.2005 and 20.04.2010.

6. Perhaps realising that no specific legal regime was in place to regulate medical devices, on 31.01.2017, MHFW notified Medical Devices Rules 2017 [hereafter referred to as "2017 Rules"], which were brought into force with effect from 01.01.2018.

7. This was followed by the issuance of the 2018 Notification on 03.12.2018, a step which was in tune with the earlier notifications issued by MHFW. The 2018 Notification proceeded to include four (4) medical devices within the definition of a drug: nebuliser, blood pressure monitoring device, digital thermometer and glucometer. The 2018 Notification kicked in from 01.01.2020.

8. At that juncture, the Association submitted its objections concerning the 2018 Notification *via* a letter dated 13.12.2018.

9. Evidently, with the advent of the 2017 Rules, the Drugs and Technical Advisory Board [hereafter referred to as "DTAB"], which has been constituted by the Central Government in the exercise of powers under Section 5 of the 1940 Act, to seek advice for itself and State Governments on technical matters, arising out of the administration of the 1940 Act and other functions, as assigned to it under the said Act, held a meeting on 02.04.2019 [hereafter referred to as, "82nd Meeting of DTAB"]. The DTAB at its 82nd meeting, formulated its advice to MHFW on the following significant matters based on the recommendation of a committee constituted on 04.02.2019:

9.1 First, regulate all medical devices under the 1940 Act, *albeit* in a phased manner; a Draft Notification in this behalf was also suggested.

9.2. Second, establish a medical device vertical concerning human resources

and infrastructure under the Central Drugs Standard Control Organization [hereafter referred to as "CDSCO"]. The advice was rendered in recognition of the fact that oversight of all medical devices would only be possible if the footprint of regulatory infrastructure is enhanced. Towards this end, a suggestion was made to induct additional human resources, which would ensure efficient and transparent regulatory services, both for licensing and enforcement, *albeit* in a balanced manner.

10. The objection captured in the 13.12.2018 communication, which was directed against the 2018 Notification, was followed by a letter dated 16.04.2019. This communication referred to the decision taken in the 82nd Meeting of the DTAB on 02.04.2019.

11. Continuing with the earlier pattern, on 16.10.2019, MHFW issued yet another Notification, which brought the ultrasound equipment within the scope of the expression drug.

12. In consonance with the advice rendered by the DTAB on 18.10.2019, the MHFW, in the exercise of powers under Sections 12 and 33 of the 1940 Act, published Draft Rules further amending the 2017 Rules, to invite objections and suggestions.

12.1 Besides this, on the same date, i.e., 18.10.2019, MHFW published the draft of the Notification that it intended to issue for bringing all medical devices within the ambit of the term drug, as defined in the 1940 Act. The Draft Notification invited objections/suggestions/comments concerning the same.

13. The Association avers that on 23.10.2019, it submitted a representation to the Prime Minister's Office [hereafter referred to as "PMO"] objecting to

the proposed Notification.

14. It appears that the Association, in addition, lodged its grievances through the online portal on 21.11.2019 as well.

15. The grievances articulated on behalf of the Association to the Draft Notification received a response from MHFW via communication dated 17.12.2019.

15.1. This was followed by the issuance of the 1st 2020 Notification, as noticed above, on 11.02.2020, whereby MHFW brought all medical devices within the ambit of Section 3(b)(iv) of the 1940 Act. In tandem, on the same date, i.e., 11.02.2020, Notification No. GSR 102(E) [hereafter referred to as "2nd 2020 Notification"] was issued by MHFW, amending the 2017 Rules.

16. The Association, perhaps, was not satisfied with the response that it received from MHFW and therefore took recourse to the Right to Information Act, 2005 [hereafter referred to as "2005 Act"] by preferring an application dated 19.03.2020, which was lodged with the Deputy Drugs Controller, Director General of Health Services (DGHS), CDSCO.

17. The sum and substance of the slew of representations and applications tendered by the Association was to flag the objections to the Draft Notification dated 18.10.2019.

18. Thus, the grievance of the Association, in a nutshell, was that via the 1st 2020 Notification, the Central Government, instead of specifying specific devices as drugs, spread the net to include all devices that were used for one or more specific purposes indicated in the said Notification; the only exception being medical devices mentioned in Annexure to the 8th Schedule to the 2017 Rules.

19. While the response to the RTI application was pending, on 31.03.2020, the National Pharmaceutical Pricing Authority [hereafter referred to as "NPPA"], i.e., the National Regulator for drugs, issued a Notification specifying that medical devices will be governed by provisions of Drug (Price Control) Order 2013. NPPA has issued the said Notification against the backdrop of the 1st 2020 Notification issued by MHFW, whereby all medical devices used on human beings and animals were notified as drugs with effect from 01.04.2020.

20. On 03.06.2020, the DGHS/CDSCO responded to the RTI application dated 19.03.2020. *Inter alia*, via the communication dated 03.06.2020, DGHS/CGSCO indicated that the 2017 Rules were aligned to international regulatory practices and provided comprehensive legislation to enable the regulation of medical devices.

20.1 Furthermore, the response went on to indicate- at that point in time, medical devices falling into thirty-seven (37) categories had been brought under the sway of the 1940 Act and the 2017 Rules. Accordingly, reference to these devices was made in the response

20.2. Besides this, it was also indicated that having regard to the importance of medical technology in healthcare and delivery, MHFW had prepared a roadmap and published Draft Rules dated 18.10.2019 (to which we have referred hereinabove) to regulate all medical devices, albeit in a phase-wise manner. According to the response, the purpose was that all medical devices placed in the market are safe and quality compliant, as per standard norms stipulated in that behalf.

20.3 In addition, reference was also made to the fact that MHFW had issued

a notification to specify devices intended for use in humans and animals as drugs, effective 01.04.2020 only after having consulted DTAB.

20.4 The response went on to state that to regulate non-notified medical devices, MHFW had issued the 2nd 2020 Notification to amend the 2017 Rules. It was conveyed that all non-notified medical devices, effective 01.04.2020, would have to be registered with the Central Licensing Authority [hereafter referred to as "CLA"] via an online portal established by CDSCO. The response stated that upon successful registration with CDSCO, the system would generate a number, which the applicant would have to affix to the medical device. It was made clear that for 18 months, there would be leeway provided to the manufacturer/exporter, i.e., the applicant, regarding the registration, which would morph into a mandatory requirement after the said timeframe expires.

20.5 Furthermore, the response indicated that for class A and B medical devices, categorised as low-risk and low-moderate risk, respectively, the exemption would cease after the expiry of 30 months from the date of issuance of the 2nd 2020 Notification. Likewise, for class C and D medical devices categorised as high-moderate risk and high risk, respectively, it was indicated that the exemption would expire after 42 months from the date of issuance of the 2nd 2020 Notification.

20.6 It was also highlighted that under the 2017 Rules, the medical devices are required to conform to standards laid down either by the Bureau of Indian Standards [hereafter referred to as "BIS"] or those that the Central Government notifies from time to time and if no such standards are available, then, the standards provided by international Organization For

Standardization [hereafter referred to as, “ISO”] or the International Electro-Technical Commission [hereafter referred to as “IEC] or standards provided in any other pharmacopeial would apply.

20.7. The communication stated that if the standards framed by the said organisations did not reference the medical device in issue, it would conform to the validated manufacturer’s standards. It was further conveyed that not only had MHFW designated five (5) laboratories as Central Medical Testing Laboratories but also the fact that seven (7) Medical Device Testing Laboratories had been registered by the Drug Controller’s office. It was also indicated that the applicants must visit the CDSCO’s website for further information.

21. At this juncture, it may be relevant to note that, in the interregnum [i.e., before the receipt of the communication dated 03.06.2020], the Association, after coming across reports in the media concerning the introduction of a Bill concerning medical devices, had filed on 08.11.2019 and 19.11.2019, applications under the RTI Act with Niti Aayog and CDSCO (HQ) DGHS. Although the Association received a response dated 23.12.2019 from CDSCO via the Deputy Drugs Controller, no response was received from Niti Aayog.

21.1 The petitioner claims it had also submitted representations on 14.11.2019 and 30.11.2019 regarding the proposal to notify all devices as drugs under the 1940 Act.

21.2 The Association also avers that on 18.12.2019, Niti Aayog had planned a consultation for key industry stakeholders to discuss the proposed legislation, i.e., the Draft Medical Devices (Safety, Effectiveness

Innovation) Bill 2019.

22. According to the Association, in August 2020, Niti Aayog circulated for internal discussion the Draft Medical Devices (Safety, Effectiveness Innovation) Bill 2020 after several rounds of discussion with MHFW.

22.1 This Bill has yet to morph into an Act, a fact which the Association does not dispute. The record shows that, just before the institution of the 2020 writ petition, the Association appears to have submitted four representations dated 02.12.2020, 05.12.2020, 08.12.2020 and 11.12.2020 concerning the regulation of notified medical devices under the 1940 Act.

Submissions of Counsels:

23. Against the backdrop of the above-mentioned facts and circumstances, Mr Adit Pujari made the following broad submissions on behalf of the Association:

23.1. The four devices that were brought within the ambit of the 1940 Act, i.e., the blood pressure monitor, digital thermometer, glucometer and nebuliser, were already regulated either under a statute or a standard fixed by a recognised organisation and, therefore, there was no need to bring the said devices within the ambit of Section 3(b)(iv) of the 1940 Act. In this context, our attention was drawn to the fact that BP monitors and digital thermometers were regulated under the Legal Metrology Act 2009 and the rules framed thereunder, while glucometers were regulated under standards notified by BIS and CDSCO. Insofar as nebulisers were concerned, it was conveyed that regulation was not required because it was an apparatus that merely dispensed liquid medicine in mist form without changing the medicinal properties.

23.2 It is contended that the impugned action, whereby the aforementioned products were regulated, as against the process was manifestly arbitrary, as it worked to the disadvantage of small and medium-scale manufacturers, importers and traders.

23.3 The decision to bring the aforementioned medical devices within the ambit of Section 3(b)(iv) of the 1940 Act was taken at the 80th meeting of DTAB. The agenda fixed for the said meeting only adverted to two (2) out of the four (4) medical devices, i.e., BP monitoring device and thermometer. There was no reference to the nebuliser and glucometer. These devices were brought into the ambit of Section 3(b)(iv) of the 1940 Act without effective consultation and without affording time to the public to object to their inclusion. Since DTAB did not include a subject matter specialist, this was an obvious case of arbitrariness.

23.4 The proposal to constitute the Medical Devices Technical Advisory Board was floated to onboard a subject matter specialist. Medical devices are distinct and separate from drugs. Therefore, there is a need to onboard a subject matter specialist, who would be able to deliberate and discuss the pros and cons of a given device before it is notified. An illustration of such a constructive approach is found in the decision taken to constitute a Board (which includes a subject matter expert) for ascertaining the efficacy of ayurvedic drugs.

23.5 The 1st 2020 Notification has made it worse by bringing all devices within the purview of Section 3(b)(iv). This decision is both manifestly arbitrary and unreasonable on the following grounds:

(i) First, there was no effective consultation, which, perhaps, was the case

when Notifications were issued from time to time to bring specific devices within the ambit of Section 3(b)(iv) of the 1940 Act.

(ii) Second, the decision to bring all medical devices within the ambit of Section 3(b)(iv) is flawed as it lacks logistical framework and support. Instead of focusing on critical medical devices, which are sterile, implantable or invasive, the respondent has spread its limited resources to bring within the sweep of the 1940 Act non-critical, non-invasive devices meant for transient use.

(iii) Third, the impugned action would have a perilous financial impact on micro, small and medium enterprises (MSMEs). Most of the MSMEs are in the business of manufacturing or importing low-risk medical devices.

(iv) Fourth, the unreasonableness and absurdity of the impugned action are evident from the fact that to test the drugs, the manufacturer/importer must submit three (3) times the quantity of the drug, which is part of a batch, in a given period. The preservation period for such drugs is three (3) months over the expiry date or three (3) years if no expiry date is specified. If these stipulations are applied to devices such as MRI, CT scan and ultrasound machines, it would be both absurd and unreasonable.

(v) Fifth, the representations and objections submitted vis-à-vis the impugned notifications were not considered or deliberated upon by MHFW.

(vi). Sixth, contrary to international practice, the manufacturers were not allowed to choose the risk classification of the device in issue as per intended use. The respondent did the risk classification without inviting opinions from stakeholders and industry players, rendering the impugned actions manifestly arbitrary and unreasonable. [See ***Shayara Bano v Union***

of India (2017) 9 SCC 1 and ***Asha Sharma v Chandigarh Administration*** (2011) 10 SCC 86]

(vii) Seventh, significant amendments have been undertaken under the garb of the impugned notifications.

(viii) Eighth, there has been a complete disregard for the decisions taken at the 82nd DTAB meeting, which laid down a roadmap detailing steps to shore up the existing regulatory regime governing notified medical devices.

(ix). Ninth, neither the order dated 04.02.2019 constituting the committee nor its report concerning the need for comprehensive regulation of medical devices is available on the website of the CDSCO or the respondent.

(x) Tenth, before implementation of the second phase, the necessary human resources should have been put in place for regulating all medical devices. The fact that the regulatory infrastructure, including human resources, is not in place is evident upon perusal of the counter-affidavit of UOI in the 2020 writ petition. As of 05.09.2021, only five (5) Central Government Laboratories and sixteen (16) Private Laboratories for testing medical devices had been set up. Significantly, none of the laboratories are still functional.

(xi) Eleventh, the requirement to comply with ISO 13485 for obtaining registration is flawed for the reason that it's a management standard certification, not a product standard certification. To comply with ISO 13485, the manufacturer would have to undertake heavy financial expenditure, even though he would have deployed fewer resources, including human resources and resources.

(xii) Twelfth, although on 22.07.2019, the Drugs Controller General, India,

constituted the Medical Devices Technical Group to advise CDSCO, it has not held a single meeting, nor was it consulted before issuing the 1st 2020 Notification. In contradistinction, under Section 33C of the 1940 Act, the Ayurvedic Siddha and Unani Drugs Technical Advisory Board has been constituted. Likewise, under Section 33D of the 1940 Act, the Ayurvedic, Siddha, and Unani Drugs Consultative Committee has been set up. No such Board has been set up for medical devices.

(xiii) Thirteenth, after 30.09.2021, all manufacturers/importers are required to register their devices under Chapter IIIA mandatorily, as per Rule 19A(2) of the Medical Devices (Amendment) Rules 2020, thus imposing an additional financial burden on the Association. This step is a stop-gap arrangement, which is likely to undergo further changes if the Bill on medical devices in the offing is converted into an Act. As a matter of fact, on 27.08.2021, MHFW constituted another Committee for framing the New Drugs and Cosmetics and Medical Devices Act. The terms of reference read as follows:

> *"…the committee shall undertake pre-legislative consultations and examine the present Act, previously framed Drugs and Cosmetics Bills and submit a draft document for a de-novo Drugs, Cosmetics and Medical Devices bill" by 30.11.2021."*

23.6 In support of his submissions, Mr Pujari has referred to the following judgments:

(i) ***Indian Rly. Construction Co. Ltd. v. Ajay Kumar,*** (2003) 4 SCC 579.

(ii) ***Tata Cellular v. Union of India,*** (1994) 6 SCC 651.

(iii) ***Bank of India & Ors. v. T. Jogram,*** (2007) 7 SCC 236.

(iv) ***Associated Provincial Picture Houses Ltd. v. Wednesbury***

Corporation, (1948) 1 KB 443.

(v) ***Ganesh Bank of Kurundwad Ltd. & Ors. v. Union of India & Ors.,*** (2006) 10 SCC 645.

24. Arguments on behalf of the respondent were advanced by Mr Kirtiman Singh and Mr Vikram Jetly. The submissions made by them are broadly paraphrased as follows:

(i) The submission advanced on behalf of the Association that the impugned notifications are ultra vires the provisions of Section 3(b)(iv) of the 1940 Act was misconceived. A bare perusal of the provision would show that the impugned Notification falls within its ambit.

(ii) Before issuance of the 1st 2020 Notification, the DTAB was consulted, which emerges upon a plain perusal of minutes of the 82nd Meeting of the DTAB dated 02.04.2019. The decision taken at that meeting against Additional Agenda S-2 would show that DTAB had, among other things, noted the committee's recommendations constituted by MHFW via order dated 04.02.2019. The committee recommended regulating all medical devices, albeit in a phased manner. The committee also proposed a Draft Notification containing exemptions, given the position that upon issuance of the Notification, the provisions of the 1940 Act would apply and, thus, disable the phase-wise implementation of the regulatory regime. A perusal of the very same minutes also shows that the committee had recommended a medical device vertical concerning human resources and infrastructure that would have to be embedded in CDSCO.

(iii) Thus, the medical devices are regulated under the 2017 Rules. These Rules were first published on 31.01.2017 and were brought into force nearly

one year later, i.e., with effect from 01.01.2018. The 2017 Rules align with international practices already in place for regulating medical devices.

(iv) The 2017 Rules provide for a risk-based classification. Medical devices falling in class A and B consist of those that present low and low-moderate risk, respectively, and hence, are regulated by the State Licensing Authority [hereafter referred to as "SLA"]. Insofar as devices falling in class C and D are concerned, they consist of devices that present high and high-moderate risk and are regulated by CLA. The applicants, including manufacturers and importers, must upload their requests on an online portal to enable the issuance of various kinds of licenses, approvals, and clinical performance evaluations of in-vitro diagnostic devices. The 1st 2020 Notification, as indicated above, provides for phase-wise regulation of medical devices that are not part of the licensing regime. A transition period of thirty (30) months was given under the 2nd 2020 Notification regarding medical devices falling under Class A and B. The thirty (30) months provided for transitioning would include eighteen (18) months for voluntary registration and twelve (12) months for mandatory registration. This period was enhanced to forty-two (42) months for those devices that fell in class C and D. Thus, the licensing regime for Class A and B devices under the 1st 2020 Notification became effective from 01.10.2022. In contrast, for class C and D devices, it will become effective from 01.10.2023.

(v). Towards this end, twenty-six (26) categories of medical devices, such as neurological, oncology, gastroenterology, nephrology and renal care, have been classified in consultation with stakeholders to enable easy filing of applications. These lists are uploaded from time to time on CDSCO's

website, i.e., https://cdsco.gov.in

(vi) Insofar as Class A medical devices are concerned, these are to be audited within 120 days of the grant of license by the SLA. However, for Class B medical devices, an audit is required to be carried out before granting manufacturing licenses. At present, there are eleven (11) notified bodies registered with CDSCO. The notified bodies are accredited by the National Accreditation Board for Certification Bodies (NABCB). These bodies are mandated with the authority to carry out audits. Besides this, five (5) Central Medical Device Testing Laboratories [hereafter referred to as, "CMDTL"] have been notified for statutory testing. In addition, twenty-four (24) Medical Device Testing Laboratories [hereafter referred to as "MDTL"] have been registered to carry out testing or evaluation of a medical device on behalf of the manufacturer under the 2017 Rules.

(vii) The medical devices are also required to conform to the standards laid down by BIS or as may be notified by the Central Government from time to time. If such standards are unavailable, then standards stipulated by ISO, IEC or any other pharmacopoeial would apply. If the device is not covered by any of the standards referred to hereinabove, it must conform to the validated manufacturer standard.

(viii) The respondent has also prepared the following guidance document for medical devices and In-Vitro Diagnostics:

> *"(i). Guidance documents & Frequently Asked Questions (FAQ) on medical devices and in vitro diagnostics is uploaded on CDSCO website.*
> *(ii). Guidance document on Grouping of Medical Devices and IVDs.*
> *(iii) Essential Principle for Safety of Performance of Medical Devices uploaded in the CDSCO website.*
> *(iv) Guidance document on Grouping of Medical Device uploaded on CDSCO website.*

(v) Classification of Medical Devices and IVDs has been finalized in consultation with the stakeholders and uploaded in the CDSCO website.
(vi) Draft Guidance document on Guidance on Post-Market Surveillance of In-vitro Diagnostic Medical Device (IVDMD).
(vii) Draft Guidance document on Guidance on Stability Studies of In-Vitro Diagnostic Medical Device (IVDMD).
(viii) Draft Guidance document on Overview on Performance Evaluation/External Evaluation of In vitro Diagnostic Medical Device (IVDMD).”

(ix) Insofar as training is concerned, the respondent has conducted more than twenty (20) training programmes, region-wise, to cover all states, central regulators and other stakeholders including importers and manufacturers. The object behind these trainings is to carry out smooth implementation of 2017 Rules and to enable easy operability of the online system/portal crafted for medical devices.

24.1. Insofar as human resources were concerned, Mr Singh and Mr Jetly indicated the following:

(i). Two hundred thirty-six (236) Medical Device Officers (MDOs) had been notified up until that date.

(ii) The medical device division had twenty-three (23) Drug Inspectors (Medical Devices) who had a background in engineering and three (3) ADC (Medical Devices).

(iii) Out of seven hundred fifty-four (754) proposed posts, in the first phase, four hundred forty-nine (449) posts are to be created. The Department of Expenditure [hereafter referred to as “DOE”] has already approved the creation of two hundred nineteen (219) posts.

24.2. Concerning the submission that the fee is exorbitant and the process is complicated, Mr Singh and Mr Jetly submitted that the fees stipulated are

much lower than those imposed in other countries.

24.3. It is further submitted the respondent's attempt is to bring all medical devices within a regulatory regime bearing in mind patient safety. The 2017 Rules are aligned with the international regulatory regime, and the Rules are configured having regard to the risk that the medical device can present. The 2nd 2020 Notification provided a transition period to enable the licensing regime to kick in without causing difficulties for those who may have to set their house in order.

24.4 In sum, Mr Singh and Mr Jetly submitted that the argument advanced on behalf of the Association that the impugned notifications were beyond the purview of the provisions of Section 3(b)(iv) of the 1940 Act is untenable and misconceived.

24.5. In support of their submissions, Mr Singh and Mr Jetly have referred to the following judgments:

(i) ***M/s Prag Ice and Oil Mills and Anr. v. UOI***, (1978) 3 SCC 459.

(ii) ***S.P. Gupta v. Union of India,*** (1981) Supp SCC 87.

(iii) ***RBI v. Peerless General Finance & Investment Co. Ltd. and Ors.,*** (1987) 1 SCC 424.

(iv) Judgment dated 27.05.2021 in WP (Crl.) 975/2021, titled ***Matrix Cellular (International) Services Limited v. State (NCT of Delhi).***

(v) ***Pharmacy Council of India v. Dr. S.K. Toshniwal Educational Trusts Vidarbha Institute of Pharmacy and Ors.*** (2021) 10 SCC 657.

Reasons and Analysis

25. We have heard the learned counsel for the parties and perused the record. The submissions advanced by the counsels can be divided broadly

into two halves.

25.1 First, whether Section 3(b)(iv) and Section 5(2) of the 1940 Act are unconstitutional inasmuch as they are violative of Articles 14 and 21 of the Constitution. Tied in with this submission is the challenge laid to the impugned notifications. The Association seeks quashing or, in the alternative, a direction to read down the aforementioned provisions and the impugned notifications.

25.2 Second, whether the implementation of the impugned notifications had placed an onerous burden, both in terms of finance and otherwise, on the stakeholders.

26. To answer the first issue, it would be relevant to extract that part of Section 3(b), which is the cause of much disquiet within the Association.

> *"**3. Definitions**.- In this Act, unless there is anything repugnant in the subject or context, -*
>
> ***xxx*** ***xxx*** ***xxx***
>
> *(b) "drug" includes-*
>
> ***xxx*** ***xxx*** ***xxx***
>
> *(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…"*

26.1 A careful perusal of sub-clause (iv) of Section 3(b) would show that the Central Government has been given leeway to bring within the ambit of the expression "drug", "such devices" which are intended for internal and external use in the diagnosis, treatment, mitigation or prevention of disease or disorder both in human beings or animals, albeit, after consultation with the Board, i.e., DTAB. The DTAB is an authority that the Central

Government is empowered to constitute for seeking advice, both for itself and the State Government, on technical matters arising out of the administration of the 1940 Act and other functions assigned to it under the said Act.

27. The narration of facts and events shows that the Central Government has been taking recourse to Section 3(b)(iv) from time to time to notify medical devices as drugs. Before the impugned notifications, the MHFW has in the past issued notifications dated 17.03.1989, 27.08.2002, 06.10.2005 and 25.01.2016. Via these notifications, MHFW classified fifteen (15) categories of medical devices as drugs. Therefore, according to us, the route is both tried and tested.

28. The argument advanced on behalf of the Association thus boils down to this, i.e., the expression "such devices" cannot include all devices, which is the ambit of the 1st 2020 Notification.

29. According to us, this submission is fallacious as the expression "such devices" has to be read with the latter part of the sub-clause (iv), which alludes to the devices as may be specified by the Central Government by Notification in the Official Gazette after consultation with the Board.

29.1. We find no words of limitation in the provision that would have us confine the expression "such devices" to some and not all devices. In this regard, the statute has conferred the necessary power on the Central Government, ring-fenced with the obligation to consult the DTAB, i.e., the expert body.

30. The other strand of the objection mentioned above is that it is, perhaps, a knee-jerk and an ill-thought move whereby all devices, at one go, have been

brought within the scope of the definition of the term "drug".

30.1 In this regard, it is vital to bear in mind that the decision to bring all medical devices within the ambit of Section 3(b)(iv) was both calibrated and thought through, as evident from the record placed before us.

31. As noticed hereinabove, MHFW had constituted an expert committee via order dated 04.02.2019 to bring all non-notified medical devices under the regulatory regime. The record also shows that the committee met various stakeholders on 08.02.2019. The stakeholders with which the committee interfaced were Association of Indian Medical Device Industry (AIMED), Federation of Indian Chambers of Commerce & Industry (FICCI), Confederation of Indian Industry (CII), Medical Technology Association of India (MTaI), American Chamber of Commerce in India (AMCHAM), US-India Business Council (USIBC) and Advanced Medical Technology Association (AdvaMed), etcetera. This meeting was followed by the committee's interaction on 12.02.2019 with officials of various departments such as the Niti Aayog, Departments of Pharmaceuticals, Department of Biotechnology, Indian Council for Medical Research and BIS.

32. Based on its interactions, the committee made its recommendation for bringing the non-notified medical devices within the ambit of Section 3(b)(iv) of the 1940 Act broadly in the following manner:

(i) In the first phase, the manufacturers and importers were to register the details of their devices with a designated portal, i.e., Sugam. For the first eighteen (18) months from the date of the intended Notification, the registration would be voluntary and, thereafter, attain mandatory connotations. During this period, the manufacturers and importers are

obliged to report Serious Adverse Events [hereafter referred to as "SAEs"] to CDSCO as well as the materiovigilance programme of India to enable these authorities to analyse such reports from the point of view of safety and efficacious performance of the devices and wherever necessary to make appropriate regulatory intervention having regard to patient safety. Likewise, the applicants should also be required to report failure in the quality management system, design, and product quality to CDSCO so that appropriate investigation and regulatory interventions can be made to ensure the quality, safety and performance of medical devices marketed in the country.

(ii) In the second phase, insofar as Class A and B medical devices were concerned, it was recommended that mandatory licensing should be achieved within twelve (12) months after the completion of eighteen (18) months from the date of the registration. Thus, after the completion of the twelve (12) months, no person, company or organisation, as per the recommendation made, should be allowed to manufacture, import, sell or distribute Class A and B medical devices without prior licensing under the 2017 Rules.

(iii) The third phase was reserved for Class C and D devices. In the case of these devices, mandatory licensing was extended to twenty-four (24) months after the completion of eighteen (18) months from the date of registration.

(iv) As in the case of Class A and B devices, it was recommended that after the completion of twenty-four (24) months, i.e., the mandatory licensing period, no person, company, or Association could manufacture, import, sell or distribute Class C and D devices without a prior license

obtained under the 2017 Rules.

32.1 A road map was, accordingly, drawn up by MHFW, which was embedded in the Draft Rules published on 18.10.2019.

32.2 It is against this backdrop that the 2nd 2020 Notification was issued. Resultantly, insofar as Class A and B devices were concerned, they had a transition period of thirty (30) months available to them, whereas, for devices that fell in Classes C and D, the transition period accorded was forty-two (42) months. These recommendations resulted in MHFW amending the 2017 Rules, the draft of which was circulated, as noticed above, on 18.10.2019, as required under Section 12(1) and 33(1) of the 1940 Act. The amendment of the 2017 Rules was brought about via the 2nd 2020 Notification only after objections received were considered.

32.3. Thus, under the 2nd 2020 Notification read with the amended 2017 Rules, the requirement to obtain a license for Class A and B devices kicked in from 01.10.2022 and insofar as Class C and D devices were concerned, licenses will have to be obtained by 01.10.2023. In our view, MHFW has granted sufficient time to manufacturers, importers, sellers and distributors sufficient time to transition to a regulatory regime. The 2nd 2020 Notification was necessitated, as with the issuance of the 1st 2020 Notification, the provisions of the 1940 Act would have straightaway become applicable for all manufacturers unless exemption was granted to enable the applicants to transition to the amended regime.

33. MHFW, in its wisdom, thought it fit to bring all medical devices within the ambit of the expression “drug”. This is clearly a policy matter. As long as MHFW has the power to do so, no fault can be found with the 1st

2020 Notification whereby all medical devices were brought within the purview of the expression "drug". MHFW's reasons are manifold, which include the desire to align itself with the international regulatory regime and to further the interest of the patients. Mere errors, if any, in the policy, which is otherwise robust and devised bearing in mind patient safety, cannot be upturned by the court while exercising the power of judicial review under Article 226 of the Constitution, unless it is a clear case of demonstrable violation of fundamental rights, including Article 14 and 21 of the Constitution. The following observations of the US Supreme Court in ***Metropolis Theatre Company v City of Chicago***, 57 L. Ed. 730 @734: 228 US 61 (1913) being apposite, are set forth hereafter:

> *"The problems of government are practical ones and may justify, if they do not require, rough accommodations,— illogical, it may be, and unscientific. But even such criticism should not be hastily expressed. What is best is not always discernible; the wisdom of any choice may be disputed or condemned. Mere errors of government are not subject to our judicial review."*

[cited, with approval, in ***State of Orissa and Ors. v Gopinath Dash*** 2005 13 SCC 495 @ 92, (paras 5-8)]

34. One can hardly quibble with the decisions cited by Mr Pujari; however, they would not apply to the facts and circumstances obtaining in the present case.

35. As far as implementation of the policy is concerned, the same, as noticed above, was calibrated, giving ample time to the applicants, i.e., the manufacturers, importers, sellers and distributors, to transition to a mandatory licensing regime. Thus, in our opinion, neither the

conceptualisation of the policy to bring all medical devices within the ambit of the expression "drug" nor its execution in three phases could be construed as manifestly arbitrary, as contended on behalf of the Association.

36. The argument of the Association concerning the impugned notifications is, broadly, as follows:

36.1 The 2018 Notification, which was based on the recommendation made at the 80th Meeting of the DTAB held on 25.07.2018, went beyond the agenda fixed for the meeting. Although the agenda for the meeting required consideration of the proposal to notify blood pressure monitoring devices and digital thermometer as medical devices under Section 3(b)(iv) of the 1940 Act, the DTAB agreed to also notify nebuliser and glucometer as medical devices under the said provision. Thus, the Notification of nebulisers and glucometers as medical devices was carried out without adequate and effective consultation.

36.2 Likewise, insofar as the 1st 2020 Notification is concerned, it is argued that the decision to bring all medical devices within the regulatory regime was not what was intended when sub-clause (iv) was inserted in Clause (b) of Section 3.

36.3 In a nutshell, the Association argues that the 1st 2020 Notification is a case of overbreadth, which was an aspect not envisaged under the provisions of Section 3(b)(iv) of the 1940 Act.

37. Regarding the first aspect, which concerns the inclusion of nebulisers and glucometers, one must note that these are simple home medical appliances/devices that are freely available for introducing drugs and monitoring drug dosage.

37.1 The devices, by themselves, are not complicated contraptions but certainly require standardisation. Errors made could lead to fatalities. For instance, if, in a given case, the glucometer is faulty, it could show the presence of blood sugar at a higher level than what is obtaining in a patient's body, compelling the patient to take a higher dosage of the prescribed drug leading to rapid fall in the blood sugar level, i.e., hypoglycemia. Hypoglycemia can cause cognitive disruptions, and coma and sometimes lead to a patient's death.

37.2. Likewise, a faulty nebuliser, for, say, an asthma patient, could cause immense distress or even death in an emergency.

38. The DTAB is an expert statutory body constituted by the Central Government for seeking advice on technical matters. The fact that the MHFW chose to include nebulisers and glucometers in the proposals that were being considered for Notification under Section 3(b)(iv) of the 1940 Act would not by itself render it illegal. The presumption [without any material to the contrary being shown to us] can only be that DTAB had the requisite technical input available to it for advising the MHFW that nebulisers and glucometers should also be notified as medical devices. Insofar as glucometers are concerned, it is the respondent's stand that the regulatory regime already covers the blood glucose strips and, therefore, bringing in glucometer within its ambit was the next logical step.

39. Insofar as the Notification of digital thermometers is concerned, one of the reasons provided by the respondent is that India had ratified the Minamata Convention on Mercury, which is a global framework put in place to protect human health and the environment from anthropogenic emissions

and release of Mercury compounds. According to the respondent, with the ratification of the convention on 18.05.2017, India's obligation under the convention was triggered from 16.08.2017, requiring it to shift to non-mercury-based devices. Therefore, it was incumbent to bring thermometers, which is also a home appliance, within the ambit of the provisions of Section 3(b)(iv) of the 1940 Act. Thus, even though these four devices are simple home appliances, a decision was taken by the MHFW to bring them within the ambit of Section 3(b)(iv) of the 1940 Act as the commencement and continuation of drug therapy in a patient was acutely dependent on the correct measurements of human vitals by these devices.

40. Therefore, according to us, the 2018 Notification is sustainable and cannot be found fault with only because it included two other devices, i.e., nebuliser and glucometer, which were initially not on the agenda of the 80th DTAB meeting.

41. The fact that the Legal Metrology Act, 2009 covers certain devices such as blood pressure monitors and digital thermometers or that the glucometers are required to adhere to the standards stipulated by BIS would not render the 2018 Notification invalid. At worst, it could be a case of over-regulation, but that by itself would not result in the 2018 Notification being declared invalid in the eyes of the law.

41.1 We may note that insofar as the Legal Metrology Act, 2009 is concerned, it is broadly concerned with the aspects relating to labelling and does not allude to quality and safety issues.

42. Likewise, it is relevant to note that Rule 7[1] of the 2017 Rules, *among other things,* requires the medical devices to adhere to the standards set by BIS or those that the Central Government/MHFW may notify from time to time. The rule also provides that if BIS or the Central Government has not stipulated a standard for a particular medical device, it shall conform to the standard specified by ISO, IEC, or other pharmacopeial standards.

42.1 If none of the aforementioned organisations have framed a standard for a particular device, then Rule 7 requires the device to conform to the validated manufacturer's standards.

42.2 Given this position, we are not persuaded to accept the submission advanced on behalf of the Association that the 2018 Notification should be struck down on the ground that it is regulated by other Acts and standards stipulated by BIS.

43. This brings us to the argument that the fee fixed for obtaining license permission or registration certificate is onerous and steep. According to us, this argument is untenable for two reasons.

43.1 First, no facts have been pleaded in the petitions to demonstrate how the alleged financial burden is onerous.

43.2 Second, a broad perusal of the Second (2nd) Schedule appended to the

[1] **Product standards for medical device**.-(1) The medical device shall conform to the standards laid down by the Bureau of Indian Standards established under section 3 of the Bureau of Indian Standards Act, 1985 (63 of 1985) or as may be notified by the Ministry of Health and Family Welfare in the Central Government, from time to time.
(2) Where no relevant Standard of any medical device has been laid down under sub-rule (1), such device shall conform to the standard laid down by the International Organisation for Standardisation (ISO) or the International Electro Technical Commission (IEC), or by any other pharmacopoeial standards.
(3) In case of the standards which have not been specified under sub-rule (1) and sub-rule (2), the device shall conform to the validated manufacturer's standards.

2017 Rules would show that the burden of the fee is dependent on the risk attached and whether or not the medical device is manufactured in India. Thus, insofar as Class A and B medical devices manufactured in India are concerned, which fall in the category of low risk and low-moderate risk, the fee is one-tenth for obtaining a "one site" license and half of what is stipulated for "each distinct medical device" falling under Class C and D. [See Rule 20(2),21(2) and 29(1) of the 2017 Rules, along with the Second (2nd) Schedule].

43.3 Compared with imported medical devices, although the fee burden is higher, the distinction between Class A and B devices [i.e., the low and low-moderate risk devices] and Class C and D devices [i.e., high-moderate and high-risk devices] is maintained. The Association has attempted to drive home the point concerning financial burden by comparing the fee imposed on locally manufactured devices with those that are imported. According to us, they fall into different slots; hence, the financial burden by way of fee imposed cannot be compared. This, according to us, constitutes false equivalence. The classification between medical devices manufactured locally, as against those imported, is clear and distinct and in no way a violation of Article 14 and Article 21 of the Constitution. It is the respondent's stand that one of the objectives they seek to achieve is to give a fillip to domestic production. One can hardly find fault with this approach.

44. This brings us to the argument advanced on behalf of the Association that the regulatory authorities do not have at their command sufficient human resources and infrastructure by way of laboratories. The data placed before us, as of 30.08.2022, discloses the following:

(i) Two hundred thirty-six (236) MDOs are in place.

(ii) The medical device division has in position twenty-three (23) DI(MDs) and three (3) ADC (MDs) with a background in engineering.

(iii) The DOE has already approved two hundred nineteen (219) posts. According to the respondent, the initial proposal submitted to the DOE was for seven hundred fifty-four (754) posts, out of which four hundred forty-nine (449) posts were required to be created in the first phase.

44.1. As regards laboratories, the following data is furnished:

(i) Five (5) CMDTLs have been notified for statutory testing.

(ii) Twenty-four (24) MDTLs are registered to test or evaluate medical devices on behalf of the manufacturers.

(iii) Eleven (11) notified bodies [i.e., bodies accredited by NABCB] are registered with CDSCO.

45. According to the Association, both in terms of human resources and infrastructure, the statutory authorities lack the bandwidth to implement the regulatory regime put in place by the 1940 Act and the 2017 Rules.

46. This argument could have been appreciated if specific cases were brought before us, which would have revealed gaps, if any, in the regulatory measures put in place by the concerned authorities, i.e., the SLAs/CLAs and CDSCOs.

47. Having regard to the fact that there has been a paradigm shift in policy whereby after the issuance of the 1st 2020 Notification, all medical devices have been brought within the ambit of the expression “drug”, a certain amount of leeway would have to be granted in terms of time to enable shoring up of resources.

47.1 That said, where negligence in evaluating the efficaciousness of medical devices or delay in processing the request for a license is found, the statutory authorities should not expect a free passage. The statutory authorities would have to discharge the obligations cast on them with whatever resources are available at their command. It is in their interest and their officers' interest to garner as many resources as required in terms of human resources and infrastructure for implementing and progressing what, according to us, is a wholesome policy. One cannot quibble with the intent, purpose and object with which the impugned notifications have been issued. The larger public interest, which concerns patient safety, requires that all medical devices be brought within a regulatory regime. This step, as demonstrated by the respondent, is aligned with the regulatory regime in various jurisdictions across the world.

48. The relief sought vis-à-vis Section 5(2) of the 1940 Act broadly veers around the absence of a medical device industry representative in the 82nd meeting of the DTAB. The DTAB, which advised the issuance of the 1st 2020 Notification in its 82nd meeting, included, amongst others, Members connected with the Pharmaceutical Industry and those associated with pharmaceutics and pharmacokinetics. The advice was based on the committee's recommendation [as noted before] constituted via an order dated 04.02.2019 issued by the Central Government/MHFW, which interacted with several stakeholders from the industry and government departments. Therefore, this argument by itself does not persuade us to hold that the advice rendered by the DTAB to the government was in any manner flawed on account of its constitution alone.

49. There is nothing to show that there has been a violation of Article 21 of the Constitution. The argument that the regime put in place by the respondent will increase prices and thus impact the right to health, seems nebulous, as, firstly, no data has been placed on the impact of the fee imposed on users of medical devices and secondly, since the Association, comprises manufacturers importers and traders, the prospective users i.e., the patients are not represented.

50. The other argument that the policy shift should have confined itself to critical medical devices as against non-critical devices meant for transient use is also misconceived as the shift in policy is, firstly, based on expert advice rendered by DTAB and secondly, is in public weal and therefore, in our view, requires no intercession.

51. The submission that the Association's objections were not considered does not appear to be accurate. The respondent, even before the 2017 Rules were amended, had published the Draft Rules dated 18.10.2019, whereby objections were invited.

Conclusion:

52. Thus, for the foregoing reasons, no interference is called for with the impugned notifications. The Association has failed to demonstrate that Sections 3(b)(iv) and 5(2) are violative of Article 14 and/or 21 of the Constitution. To our minds, there is no manifest arbitrariness or unreasonableness in the shift in policy of bringing all medical devices within the ambit of a regulatory regime.

53. Our postscript is, if we were to allow the writ petition, figuratively speaking, we would be throwing away the baby with the bathwater. That

said, the respondent should take measures to quickly iron out the kinks found while progressing the regulatory regime.

54. Accordingly, the writ petitions are closed, leaving the parties to bear their respective costs.

55. Consequently, the pending applications shall stand closed.

(RAJIV SHAKDHER)
JUDGE

(TARA VITASTA GANJU)
JUDGE

SEPTEMBER 1st, 2023
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