THE NEW CONSUMER PROTECTION LAW AND ITS IMPACT ON THE MEDICAL DEVICE REGULATORY FRAMEWORK

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ABSTRACT

India's new consumer protection legislation, the Consumer Protection Act, 2019 ("CPA, 2019") has had a significant impact on all industries, from consumer goods to real estate, and the medical device industry is no exception. However, the industry is uniquely placed in comparison to other mainstream sectors such as automobiles and consumer goods, in that the industry is already regulated under a special legislation i.e., the Medical Device Rules, 2017 ("MDR"). In this paper, we have provided an overview of the CPA, 2019 and the MDR, and the areas in which they overlap. By undertaking this comparison, we aim to understand the combined impact of these regulations on the medical device industry. Further, we have identified areas where there may be conflict between the CPA, 2019 and the MDR and proposed appropriate solutions for such situations.

I. INTRODUCTION

The Consumer Protection Act, 2019 ("**CPA, 2019**"), which replaced the Consumer Protection Act, 1986 (**"CPA, 1986"**) as of July 2020, has become the primary consumer protection legislation in India.[1] The CPA, 2019 is considerably more comprehensive than its predecessor and a revamp of the law had been much awaited, considering the numerous developments that have taken place over the three decades since the enactment of the CPA, 1986. The increasing reliance of technology in

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They acknowledge the assistance by Ms. Anjuri Saxena, IV Year Student, Rajiv Gandhi National University of Law, Punjab.
[1] Ministry Of Consumer Affairs, Food And Public Distribution, Government of India, *Consumer Protection Act, 2019*, available at http://egazette.nic.in/WriteReadData/2020/220546.pdf, last seen on 16/01/2021; Ministry Of Consumer Affairs, Food And Public Distribution, Government of India, available at http://egazette.nic.in/WriteReadData/2020/220657.pdf, last seen on 16/01/2021.

everyday life as well as the introduction of several healthcare products intended for direct use by consumers had called for greater accountability of companies operating in these sectors.

A more specific product liability regime as well as a consumer authority were, therefore, welcome introductions to the CPA, 2019. There are now specific provisions addressing product liability and delineates when the product manufacturer, product seller and product service provider would be held liable to pay compensation for any harm caused by a defective product manufactured by a product manufacturer, serviced by a product service provider or sold by a product seller.[2]

The CPA, 2019 also establishes the Central Consumer Protection Authority (**"CCPA"**) as the regulator responsible for protecting consumer rights.[3] This includes enforcing the rights of consumers as a class, preventing unfair trade practices and ensuring that no false advertisements are made in respect of goods and services.[4] The CCPA also has the power to initiate product recalls and initiate an inquiry or investigation into alleged violations of consumer rights or unfair trade practices either on its own initiative or based on a complaint received from consumers.[5]

The CPA, 2019 applies to all goods and services unless specifically exempted by the Central Government.[6] No goods or services have been excluded so far. As a result, the CPA, 2019 also applies to medical devices. It should be noted here that medical devices are specifically regulated under a specific regulatory framework i.e., the Medical Device Rules, 2017 ("**MDR**") administered by the Central Drugs Standard Control Organization (**"CDSCO"**).

Due to this, there is some overlap in the functions exercised by the CCPA and the CDSCO in respect of medical devices. In this article, we have attempted to provide an overview of the applicable regulatory framework

[2] Chapter VI, The Consumer Protection Act, 2019; S. 82, The Consumer Protection Act, 2019.
[3] Ministry of Consumer Affairs, Food and Public Distribution, Government of India, available at http://egazette.nic.in/WriteReadData/2020/220659.pdf, last seen on 16/01/2021, last seen on 16/01/2021; S. 10, The Consumer Protection Act, 2019.
[4] S. 18, The Consumer Protection Act, 2019.
[5] S. 18 (2), The Consumer Protection Act, 2019.
[6] S. 1 (4), The Consumer Protection Act, 2019.

under the CPA, 2019 and MDR, examine the overlap between the two regulations and chart a way forward. The article begins by outlining the overlapping provisions under the CPA, 2019 and MDR in respect of medical devices as well as the overlapping duties, powers and responsibilities of the CCPA and CDSCO in relation to medical devices. Subsequently, it examines the impact of such overlapping provisions on the medical device industry and argues that in cases of such overlap, the MDR should supersede. Finally, it provides inputs on the way the legal framework should adapt to best accommodate the welfare of consumers and minimize ambiguities in enforcement mechanisms.

II. OVERLAP BETWEEN THE CPA, 2019 AND THE MDR

The CPA, 2019 and MDR were enacted with different intentions in mind. The CPA, 2019 was enacted to provide consumers with a direct remedy in the event the consumer receives a defective product or in case of an unfair trade practice. On the other hand, the MDR is intended as a more specific regulation that governs various aspects of medical devices, including its safety and efficacy. The MDR broadly sets out standards required to be followed by manufacturers/importers of medical devices and requires manufacturers, importers and sellers of medical devices to obtain the requisite licenses prior to undertaking the respective activities.

1. Product Liability

The term 'product liability' is specifically defined under the CPA, 2019 but not under the MDR.[7] Nonetheless, both the CPA, 2019 and the MDR have similar provisions dealing with liability arising out of any harm caused by a defective product. Under the CPA, 2019, product liability is defined as the *"responsibility of a product manufacturer or product seller, of any product or service, to compensate for any harm caused to a consumer by such defective product manufactured or sold or by deficiency in services relating thereto"*.[8]

[7] S. 2 (34), The Consumer Protection Act, 2019.
[8] Ibid.

The CPA, 2019 divides responsibility between the product manufacturer,[9] product seller[10] and product service provider[11].[12] Broadly, the liability is divided based on the entity who is directly responsible for causing the damage. For instance, the product manufacturer is responsible in cases of manufacturing defects, if the product is defective in design or does not conform to express warranty. [13] The product seller is liable in cases where the seller has modified the product or made an express warranty independent of a manufacturer's warranty. [14] The product service provider is liable if the service provided was not as per standards set out in law or contract. All three parties are liable in the event adequate instructions for usage were not provided. [15]

Corresponding provisions in relation to medical devices are captured under the Drugs and Cosmetics Act, 1940 (**"D&C Act"**) – the parent legislation under which the MDR is framed. The D&C Act criminalizes the import, manufacture and sale of medical devices which are (i) not of standard quality, (ii) adulterated, misbranded or spurious, and (iii) otherwise prohibited under law.[16] In the event the above-mentioned provisions are violated, the manufacturer or importer of the medical device, as the case may be, would be held liable.

It should be noted that an amendment has been proposed to the MDR under which manufacturers/importers of medical devices would be held liable in the event a medical device is found malfunctioning or not in compliance with the conditions of the license to manufacture/import granted to the manufacturer/importer, as the case may be (**"Compensation Amendment"**).[17] This compensation would likely be

[9] S. 84, The Consumer Protection Act, 2019.
[10] S. 86, The Consumer Protection Act, 2019.
[11] S. 85, The Consumer Protection Act, 2019.
[12] The term 'product service provider' is distinct from 'service provider' under the Consumer Protection Act. Unlike a service provider who provides a service in general, the product service provider provides any service in respect of a product e.g., repairs and maintenance.
[13] Supra 9.
[14] Supra 10.
[15] Supra 11.
[16] Ss. 10 and 18, The Drugs and Cosmetics Act, 1940.
[17] Minutes of the 81st Meeting of Drugs Technical Advisory Board, Central Drugs Standard Control Organization, available at

payable to the aggrieved patient (in case of injury) or the legal heirs of the patient (in case of death). The Drugs Technical Advisory Board (**"DTAB"**) – the apex body relating to technical matters in respect of drugs and medical devices – had constituted a sub-committee under the chairmanship of Dr. B.D. Athani (**"Sub-Committee"**) which is currently in the final stages of preparing its report. The Sub-Committee was constituted to examine the issue of compensation in case of faulty medical devices and present its report to the DTAB. The Sub-Committee Report reportedly recommends the establishment of a 'causality assessment committee' to determine the quantum of compensation.[18]

From the above, it can be seen that the broad grounds for holding a manufacturer liable are similar under the CPA, 2019 and MDR i.e., the product is defective in that it does not adhere to the standards required to be maintained in respect of the product under law or contract. Nonetheless, there are a few differences between the two regulations in respect of product liability, as follows:

1.1 Entity Responsible

While both the CPA, 2019 and the MDR hold the manufacturer responsible in product liability claims in some instances, the CPA, 2019 has an additional component where the product seller or product service provider may also be held liable in a product liability claim.

The MDR at present does not contain provisions under which the product service provider may be held liable. Product sellers under the MDR could be held liable in limited instances only (primarily for violation of license conditions).[19]

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=NTY2, last seen on 16/01/2021.

[18] T. Thacker, *Side effects of medical devices: Panel chalks out formula for compensation*, The Economic Times (26/09/2019), available at https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/side-effects-of-medical-devices-panel-chalks-out-formula-for-compensation/articleshow/71303722.cms?from=mdr, last seen on 16/01/2020.

[19] See Rules 30 and 38, The Medical Device Rules, 2017.

1.2 Who Can Initiate Action?

Generally, only a consumer (including consumer associations) can bring an action under the CPA, 2019.[20] It may be noted here that individuals are not deemed to be consumers under the CPA, 2019 in cases where they have purchased a good or used a service for commercial purposes, unless such individuals purchase a good or use a service solely for self-employment purposes of earning their livelihood.[21] Therefore, commercial establishments such as clinics and hospitals may not eligible to bring an action in consumer court in the event they receive a defective device.

On the other hand, any person can approach the relevant licensing authority to file a complaint in respect of a faulty medical device.[22]

1.3 Manner of Initiating Action

Under the CPA, 2019 the consumer has a direct claim against the manufacturer and if held liable, the manufacturer is required to directly compensate the consumer for harm or injury caused.[23] To initiate an action in a product liability claim, the consumer should file a complaint before the appropriate consumer forum where it will be adjudicated upon thereafter.

Under the D&C Act and MDR[24], any person who is aware of a defect in a medical device may approach the CDSCO (or any of the state-level licensing authorities (**"SLA"**) functioning under the CDSCO) to file a complaint. Following this, the CDSCO or the SLA will take action against the faulty medical device manufacturer/importer as it deems fit. This may include conducting raids or other inquiry or investigation,[25] issuing show cause notices to the relevant manufacturer/importer,[26] suspending or cancelling[27] the licenses held by the manufacturer/importer to restrain from carrying out business operations in India, and even initiating criminal

[20] S. 35, The Consumer Protection Act, 2019.
[21] S. 2 (7), The Consumer Protection Act, 2019.
[22] Rule 70 (vi), The Medical Device Rules, 2017.
[23] S. 82, The Consumer Protection Act, 2019.
[24] Rule 70, The Medical Device Rules, 2017.
[25] Rule 20 (8), The Medical Device Rules, 2017.
[26] Rule 33 (1), The Medical Device Rules, 2017.
[27] Rule 30, The Medical Device Rules, 2017.

proceedings[28] against such manufacturer/importer in a court of law. A portion of the fine imposed by the court may be directed to be paid to the affected person/legal heir. Therefore, while the ambit of persons who can make a complaint is wider than that under the CPA, 2019 the remedies available are in the nature of penal action that does not provide compensation/restitution to the complainant or other aggrieved party.

2. Product Recall

A product recall broadly refers to the process of the manufacturer/importer of a good, taking back goods that are already present in the market at different levels of the supply chain.[29] The recall usually takes place due to a deficiency in the product discovered after the good was already dispatched from the manufacturer's warehouses. A recall may be voluntary (initiated by the manufacturer/importer) or statutory (a recall directly be a regulatory/statutory authority).

Both the CPA, 2019 and the MDR have provisions relating to product recall. Under the CPA, 2019, the CCPA has the power to recall goods from the market which are hazardous, dangerous or unsafe.[30] At the moment, the CPA, 2019 does not specifically cover voluntary recalls. There is also no specific process prescribed in case of statutory recalls initiated under the direction of the CCPA. Further, given that the recall provision was not present under the CPA, 1986, there is little precedent on how a product recall should be conducted or who would be responsible for conducting such recall.

The MDR contains a skeletal procedural outline for both voluntary and statutory recalls of medical devices.[31] The MDR defines recalls as follows:

> any action taken by its manufacturer or authorized agent or supplier to remove the medical device from the market or to retrieve the medical device from any person to whom it has been supplied, because the medical device, —

[28] S. 22 (2), The Drugs and Cosmetics Act, 1940.
[29] Guidelines on Recall and Rapid Alert System For Drugs (Including Biologicals & Vaccines), Central Drugs Standard Control Organization, CDSCO/RRAS, (23/11/2012) available at https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/biologicals/4GuidelineRecalRapidAlert.pdf, last seen on 16/01/21.
[30] S. 20, The Consumer Protection Act, 2019.
[31] Rule 3 (zp), The Medical Device Rules, 2017.

(a) is hazardous to health; or
(b) fails to conform to any claim made by its manufacturer relating to its quality, safety or efficacy; or
(c) does not meet the requirements of the Act and these rules

Under the MDR, the manufacturer (in case of domestic goods) and the authorized agent of the foreign manufacturer (in case of imported goods) are responsible for the recall. The manufacturer/authorized agent is also required to inform the Central Licensing Authority (CDSCO) or the SLA in the event a medical device which may be unsafe for patients has been placed on the market.[32] The recalled medical devices are required to be destructed under the supervision of the Central Licensing Authority (CDSCO) or the SLA.[33]

The MDR comprises a product-specific process for recall while the CPA presently only provides a power to the CCPA to initiate product recall. Further, the MDR also comprises post-recall procedures on the destruction of the recalled medical devices.

3. Pricing

Medical devices are considered to be essential commodities and their prices are regulated under the Drugs (Prices Control) Order, 2013 (**"DPCO"**) administered and enforced by the National Pharmaceutical Pricing Authority (**"NPPA"**). The DPCO directly or indirectly regulates the prices of all medical devices. The NPPA fixes the ceiling price of medical devices considered to be essential (knee implants and cardiac stents are presently the only two devices in this category).[34] For all other devices, the manufacturers/importers are required to ensure that the price of such device does not increase by more than 10% in any given period.[35] All entities along the supply chain are required to display the price list conspicuously.[36] In the event the manufacturers/importers contravene the provisions of the DPCO, the NPPA is empowered to initiate proceedings

[32] Rule 26 and 38, The Medical Device Rules, 2017.
[33] Rule 80 (2), The Medical Device Rules, 2017.
[34] Rule 4 r/w 14, The Drugs (Prices Control) Order, 2013.
[35] Rule 20, The Drugs (Prices Control) Order, 2013.
[36] Rule 24 (3), The Drugs (Prices Control) Order, 2013.

against such manufacturer/importer and required the person to deposit the overcharged amount with the NPPA.[37]

The CPA, 2019 does not prescribe prices of any commodity. Nonetheless, charging a price higher than the one displayed on the good, fixed by law, or displayed on a price list exhibited by a trader as required under law is grounds for a complaint under the CPA, 2019.[38] As a result, in the event any entity along the supply chain of a medical device charges a price higher than one displayed on the medical device/the price list or higher than the maximum price that may be fixed in respect of such medical device under the DPCO, the consumer has a right to directly proceed against such entity.

The key takeaway here is that in the event of overcharging, the CPA, 2019 provides a direct remedy to the consumer to claim for the overcharged amount from the responsible entity. The DPCO, on the other hand, empowers the NPPA to commence proceedings against the manufacturer/importer of the good in respect of the overcharged amount.

III. THE WAY FORWARD

As can be seen from the previous section, the CPA, 2019 essentially gives the consumer a direct claim against the manufacturer/importer of a medical device in product liability and overcharging cases. In recall cases, the powers of the CCPA overlap with those of the CDSCO/SLA.

While providing consumers with a direct remedy against the manufacturer/importer may initially seem conducive to justice, it may create inequities from the perspective of the medical device manufacturer/importer. Some of the key considerations here are as follows:

1. Dual Penalty

In each of the above cases, the relevant regulatory authority (CDSCO/SLA/NPPA) has a separate right to initiate proceedings against the medical device manufacturer/importer while the consumer has a

[37] Rules 14, 15, 16 and 20, The Drugs (Prices Control) Order, 2013.
[38] S. 2 (6) (iv), The Consumer Protection Act, 2019.

separate claim. Due to this, two parallel claims arising out of the same set of facts may be initiated against the medical device manufacturer. As a result, the medical device manufacturer/importer may be held liable twice in respect of the same action. It is pertinent to note here that the nature of the penalty in the majority of the cases is also the same. Except for cases where the CDSCO/SLA initiates criminal prosecution against the medical device manufacturer/importer for manufacturing/importing a medical device that is adulterated, misbranded, spurious or not of standard quality, all penalties are civil in nature.

To elaborate, compensation payable to patient or legal heirs of the patient due to harm arising out of a faulty medical device is civil in nature, both under the CPA, 2019 and as per the recommendations proposed to be made by the Sub-Committee. Due to this, in the event a consumer initiates action before both the CDSCO/SLA and the consumer forum, the medical device manufacturer/importer may be held liable to pay compensation twice. In cases of overcharging, the NPPA may initiate separate proceedings against the manufacturer/importer of the medical device to recover the entirety of the overcharged amount while the consumers who have been overcharged may file several complaints in respect of the same overcharging. As a result of this, medical device manufacturers/importers, who were earlier responsible only to the regulator (who in turn represented the interests of the consumers as a whole) may now be subject to multiple suits in respect of the same set of facts.

To prevent this, it may be good to explore whether medical devices be exempt from the provisions of the CPA, 2019 dealing with overcharging and product liability. Such a move may not harm the rights of consumers as they would continue to have the power to approach the relevant regulator for addressing their grievances. Further, the medical regulatory framework is better suited to addressing such claims as it allows complaints not only from consumers but, also commercial organizations.

In the case of product recall, the CDSCO already has an established procedure for carrying out a medical device product recall. As a result, it is proposed that in the event the CCPA receives a complaint or otherwise

comes to know of a hazardous medical device being present in the market, the CCPA should approach the CDSCO to initiate a statutory recall as contemplated under the MDR. This can be incorporated as internal protocol in the CCPA's governing documents.

2. Nature of Enforcement/Adjudicating Authority

Determining liability in a medical device product liability case requires specialized and technical knowledge. Each medical device has its own medical specialization and adjudicating authorities are required to parse through volumes of evidence on the functioning of the medical device and the facts of each case to arrive at a decision. Matters are further complicated in cases where a determination needs to be made on whether the harm was caused due to a fault in the medical device or due to the faulty application of the medical device by the treating physician. Due to this, consumer forums, which are strapped for time and deal with a variety of matters, may not be best equipped to deal with medical device product liability claims.

The 'causality assessment committee' proposed to be set up under the MDR may be a better fit to determine compensation in case of injuries caused due to a faulty medical device. The Sub-Committee has also reportedly proposed a formula for calculation of compensation which may aid in quicker resolution of cases as compared to the consumer forums.[39]

IV. CONCLUSION

The CPA, 2019 is a significant positive development to ensure that consumers' rights are protected. However, as the CPA, 2019 applies to all industries, goods and services, the legislation may cause an overlap in claims for certain sectors which are already specifically regulated. The medical device industry happens to be one of them.

As a result, at least in clear cases of overlap between the CPA, 2019 and MDR, the provisions of the MDR should ideally take precedence. This will ensure both the protection of consumer rights as well as providing a more conducive business environment for the medical device industry. At the

[39] Supra 18.

CCPA's level, the CPA, 2019 already provides the option for the CCPA to forward any reports of prima facie cases to relevant sectoral regulators. If this option is used liberally, especially with respect to medical device claims, the process may in turn be beneficial for the consumer, as it widens the avenues for a consumer to raise a claim, while also being assured of a more structured process overseen by a sectoral regulator for resolution.