

The changing face of product liability regime in India and its impact on the med-tech sector

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Introduction

Technology is becoming an inseparable part of our lives with every day that passes. From the home automation device raising the blinds as we wake up, to mobile devices telling us the optimal time to go to sleep, sometimes it's difficult to imagine a world without these innovative devices. A problem with a gadget no longer stops at causing monetary loss but has other far-reaching implications.

Given how our lives have become intertwined with technology, a problem with a single cog in the wheel could cause a massive ripple effect, leading to injury, or in the worst case, even death. For example, the malfunctioning of a sensor in a fall detection monitor could lead to an unattended senior citizen succumbing to injury, merely because the monitor failed to notify emergency services of the person's details and location.

Thanks to the decreasing cost of mobile data and the exponential increase in digital penetration, India too has come a long way in adopting new evolved technologies. There has been a significant increase especially in the adoption of medical technology by consumers – from using 3D printing for manufacturing medical equipment and using tele-medicine technology to deliver healthcare at the institutional level, to increased use of health wearables and self-monitoring systems at the consumer-end level. While law generally lags somewhat behind such advancements, there is an increasing need to ensure that both patients' and consumers' rights are protected, in light of the digital era we live in. Increased use of technology and evolved devices can lead to higher instances of malfunction or defect, which certainly cannot be ignored.

The introduction of a new consumer protection law in India: the Consumer Protection Act, 2019 (CPA 2019),^[1] along with addressing issues of e-commerce and online trade, will also play a key role in the medical profession and healthcare system. What does this mean for manufacturers, service providers and the supply chain in the med-tech sector? This article will explore the introduction of a specific product liability regime, and its impact on this growing sector.

What is changing for product liability in India?

The CPA 2019 is set to replace India's existing consumer protection framework, the Consumer Protection Act, 1986 (CPA 1986).^[2] While CPA 2019 has been enacted and published, it has yet formally to take effect. Product liability action is not a new concept in India but it's a far cry from other developed jurisdictions. The CPA 1986 did provide consumers with the option of initiating action over defective products,^[3] but the Indian subcontinent has hardly heard of any class action claims, let alone in the healthcare sector. Most cases before the consumer fora tend to deal with medical negligence or non-payment issues.

However, unlike the CPA 1986, CPA 2019 has a dedicated a separate chapter which deals with product liability action. [4] This clearly demarcates product liability across the supply chain as: manufacturer, [5] product seller, [6] and product service provider. [7]

Additional remedy

The CPA 2019 also introduces a new regulator – the Central Consumer Protection Authority (CCPA), which would act as the consumer watchdog entrusted with independently investigating breaches of consumer rights as a class, [8] issuing recall orders for hazardous products [9] and imposing penalties. [10] The CCPA is yet to see the light of the day; however, amendments to the CPA 1986 and establishing such specialised body will help in strengthening the regime. In contrast, a *suo moto* action for a defective product was not built into the earlier framework and had to be initiated by aggrieved consumers before a consumer forum. This void has been addressed by the new regime.

With its aim at striking a balance between the interests of consumers and the sector, the CPA 2019 also provides certain exceptions to product liability action, [11] in circumstances where the products have been misused, or if the product being purchased by the employer, for use at the workplace, did not adhere to installation warnings or instructions, or if the nature of the product is such that the user should have known the associated risks. The legislators have attempted to reduce ambiguity to the extent possible ensuring an effective regime is put in place and that manufacturers/service providers do not escape liability.

Impact on the med-tech sector

The implementation of the CPA 2019 would be beneficial not only for the consumers but also to the extent of filling certain existing regulatory gaps in the medical device framework.

In India, medical devices are primarily regulated by the Drugs and Cosmetics Act, 1940, along with the Medical Device Rules (MDR). The MDR does not currently contain provisions for mandatory compensation to be provided to patients in the event of an adverse event, outside of a clinical trial. In addition, action under the regulatory framework can only be initiated by the drug/medical device regulator and not by an individual patient. Therefore, for a patient to claim compensation for a defective medical device, one of the few recourses available under the existing framework is to approach the consumer forum and initiate action under the CPA 1986.

With the introduction of the CPA 2019, the CCPA itself will be in a position to investigate the violation of consumers' rights independently as a whole class and initiate action for seeking compensation accordingly, in addition to imposing penalties. If the CCPA determines that a defective medical device is also hazardous, it would also be authorised to direct for the recall of the medical device from the market, thereby preventing further adverse events. This would be an additional means outside of the MDR to hold medical device manufacturers accountable for the quality of their products.

Changes ahead

As discussed, the CPA 2019 not only places liability on the product manufacturer, but also its seller and its service provider. Given the amalgamation of products and services in the med-tech sector, especially 'wearables', it is important to understand who is considered a 'product service provider' under the CPA 2019. A product service provider under the CPA is defined as 'a person who provides a service in relation to the actual product.' Therefore, a service provider who provides a service not directly in relation to the product should not be considered a product service provider, thereby not being subject to a product liability claim with respect to the product, which is a critical distinction.

This can be explained further in the same context of a malfunction with respect to a fall detection monitor. In this case, where an independent service provider provides the service of sending an ambulance if the monitor detects a fall, the emergency service provider who provides the ambulance services should not be held liable if there was a malfunction with the monitor, which is manufactured and sold by a separate entity. However, it must be remembered that a claim

for deficiency of service could still be independently initiated against the emergency service provider, if there was an issue with the service. In contrast, if a service provider is responsible for the servicing of the monitor itself (linked to the product in question), in the event of a malfunction, such a service provider could be held responsible as a product service provider.

Interaction with the healthcare sector

The medical device sector is also reliant on the healthcare sector, given that certain medical devices would need to be implanted surgically. In this case, the healthcare practitioner should be considered a product service provider with respect to the medical device. Given this, it becomes important to be able to demarcate liability between issues arising out of the manufacture of the medical device and its implantation. Since the CPA 2019 clearly lays down the instances when a product liability claim can be brought against the product manufacturer, product seller and the product service provider, it should simplify the process and help in attaching liability to the entity involved: product manufacturer or product service provider. However, with 'healthcare' being specifically excluded from 'service' under the new regime, whether it will create more confusion or lead to ascribing liability is anyone's guess.

Double-edged sword for importers

Under the CPA 2019, there are certain instances where a product seller steps into the shoes of the product manufacturer, such as where the product manufacturer is not subject to India's legislation.^[12] This is an important consideration for medical device importers from a product liability perspective, given that India's medical device sector is heavily import-driven. As the importer would be held responsible under the CPA 2019 for product liability claim, importers should focus on creating sufficient contractual protection with the foreign manufacturer to demarcate liability between them and provide for indemnification in the event of a claim.

Conclusion

Recent changes to the medical device regulatory framework should be equally beneficial for both the sector and consumers. With effect from April 2020, all medical devices (including their software) have been brought within the ambit of the MDR.^[13] Previously, only certain notified devices were regulated under this framework. The MDR prescribes specific standards to be followed for medical devices. This should help determine whether a product is defective under the CPA 2019, as it ties the standard to be maintained for a product, to that required by any other law. The addition of all medical devices within the MDR, therefore, brings certainty on the requisite standard that is required to be maintained for a product and, consequently, whether the product is defective for not meeting the prescribed standard. This would form the very premise of initiating any product liability claim.

Overall, the introduction of the new product liability regime is poised to benefit medical device consumers to a large extent, both in terms of being able to initiate a claim for compensation for a defect, as well as holding the medical device sector to a higher standard of care for their products. This also entails that medical device manufacturers should revisit product instructions, disclaimers, limitations, as well as existing and future documentation with the supply chain, to ensure that roles and responsibilities between them are clearly identified, and the demarcation of liability is clearly drawn out for each party, to avoid being dragged in a class action claim. India, unlike other developed jurisdictions does not have much jurisprudence on class action claims, let alone product liability cases. Therefore, the implementation of the new law would pave the way forward.

Notes

[1] CPA 2019, available at: <http://egazette.nic.in/WriteReadData/2019/210422.pdf> (<http://egazette.nic.in/WriteReadData/2019/210422.pdf>), last accessed 4 June 2020.

[2] CPA 1986, available at:

<https://consumeraffairs.nic.in/sites/default/files/Consumer%20Protection%20Act%201986.pdf>

(<https://consumeraffairs.nic.in/sites/default/files/Consumer%20Protection%20Act%201986.pdf>), last accessed 4 June 2020.

[3] Section 13 of the CPA 1986.

[4] Chapter VI of the CPA 2019.

[5] Section 2 (36) of CPA 2019. A 'product manufacturer' means a person who: (i) makes any product or parts thereof; or (ii) assembles parts thereof made by others; or (iii) puts or causes to be put his own mark on any products made by any other person; or (iv) makes a product and sells, distributes, leases, installs, prepares, packages, labels, markets, repairs, maintains such product or is otherwise involved in placing such product for commercial purpose; or (v) designs, produces, fabricates, constructs or remanufactures any product before its sale; or (vi) being a product seller of a product, is also a manufacturer of such product.

[6] Section 2 (37) of CPA 2019. A 'product seller', in relation to a product, means a person who, in the course of business, imports, sells, distributes, leases, installs, prepares, packages, labels, markets, repairs, maintains, or otherwise is involved in placing such product for commercial purpose and includes: (i) a manufacturer who is also a product seller; or (ii) a service provider, but does not include – (a) a seller of immovable property, unless such person is engaged in the sale of constructed house or in the construction of homes or flats; (b) a provider of professional services in any transaction in which, the sale or use of a product is only incidental thereto, but furnishing of opinion, skill or services being the essence of such transaction; (c) a person who – (I) acts only in a financial capacity with respect to the sale of the product; (II) is not a manufacturer, wholesaler, distributor, retailer, direct seller or an electronic service provider; (III) leases a product, without having a reasonable opportunity to inspect and discover defects in the product, under a lease arrangement in which the selection, possession, maintenance, and operation of the product are controlled by a person other than the lessor.

[7] Section 2 (38) of CPA 2019. A 'product service provider', in relation to a product, means a person who provides any service in respect of such product.

[8] Section 10 of the CPA 2019.

[9] Section 20 of the CPA 2019.

[10] Section 18 of the CPA 2019.

[11] Section 87 of the CPA 2019.

[12] Section 86(d) of the CPA 2019.

[13] Ministry of Health and Family Welfare, Notification, 11 February 2020, available at:

<http://egazette.nic.in/WriteReadData/2020/216073.pdf>

(<http://egazette.nic.in/WriteReadData/2020/216073.pdf>), last accessed 4 June 2020.

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