

MEDICINE AND THE LAW

The Consumer Protection Act: No-fault liability of health care providers

M Nöthling Slabbert, Michael S Pepper

The introduction of no-fault or strict liability by the Consumer Protection Act 68 of 2008 (CPA) poses serious problems in the health care context. With a patient as a 'consumer' in terms of the CPA, health care practitioners may find themselves as 'suppliers' or 'retailers' as part of a supply chain, and potentially liable for harm and loss suffered by a patient in terms of the new no-fault liability provision. The claimant (patient) can sue anyone in the supply chain in terms of this provision, which places the health care practitioner who delivered the care in a very difficult position, as he

or she is the most easily and often only identifiable person in the supply chain. Although the causal link between the harm suffered by the complainant will still need to be established on a balance of probabilities, the traditional common law obstacle requiring proof of negligence no longer applies. The article argues that this situation is unsatisfactory, as it places an increasingly onerous burden on certain health care practitioners.

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The Consumer Protection Act (No. 68 of 2008) (CPA)¹ aims to protect and develop the social and economic welfare of consumers, in particular potentially vulnerable consumers.² It applies to all transactions in South Africa that involve the supply of goods or services,³ unless exempted.⁴ The definition of a 'consumer' includes a patient.⁵ Despite its noble objectives the application of the Act to the health care sector creates practical challenges and uncertainties. Health care establishments and practitioners must ensure that they comply with the CPA's onerous and stringent requirements.

The CPA establishes eight fundamental consumer rights: right to equality in the consumer market;⁶ privacy;⁷ choice;⁸ disclosure and information;⁹ fair and responsible marketing;¹⁰ fair and honest dealing;¹¹ fair, just and reasonable terms and conditions;¹² fair value, good quality and safety;¹³ and the right to hold the supplier accountable to consumers.¹⁴ If the CPA conflicts with other concurrent health care legislation (e.g. the Health Professions Act No. 56 of 1974 or the Medical Schemes Act No. 131 of 1998), the Act offering the greater protection to the consumer will apply,¹⁵ which, without exception, favours the consumer-orientated CPA.

Key definitions illustrate the nature of the application of this legislation in the context of health care. 'Service' refers to work performed by a person for the direct or indirect benefit of another, including the provision of information, advice or consultation, e.g. consultation with a health practitioner; medical advice rendered by the practitioner, or any medical intervention, such as an operation; and the undertaking, underwriting or assumption of risk by a

person on behalf of another.¹⁶ This includes medical scheme cover and services provided under risk-sharing arrangements. A health care establishment or practitioner will, depending on the context, also be regarded as a 'supplier' in terms of the CPA. A 'supplier' is a person who markets goods or services, including individuals, juristic persons, partnerships, trusts, organs of state and public-private partnerships.³ 'Market' in this context means to 'supply' or 'promote' goods or services,³ whereas 'supply' means to sell services, or to perform services or cause them to be performed or provided. In relation to goods, 'supply' means to sell, rent, exchange or hire goods in exchange for money. 'Goods' are broadly defined and include 'anything marketed for human consumption',³ including not only medicines, but also devices and consumables.

Thus, practically all interactions between patients, health care providers and medical schemes will fall within the ambit of a CPA transaction. Depending on the context (e.g. when ordering goods from another supplier), patients and other health care providers may qualify as either consumers or 'suppliers'. (It is doubtful whether medical schemes will be regarded as consumers, since the CPA does not apply to entities the asset value or net turnover of which exceeds the threshold of R2 million.¹⁷) Patients are consumers and beneficiaries of services (e.g. medical scheme dependants).

The CPA provides that a regulatory authority (e.g. the Health Professions Council of South Africa) may apply to the Minister for an industry-wide exemption from provisions of the Act on the grounds that these provisions overlap or duplicate a regulatory scheme already in existence in terms of national legislation, treaty, international law or convention.¹⁸

No-fault liability for damage caused by goods

A contentious issue of the CPA is its strict or no-fault liability for damage caused by goods. A consumer has the right to expect that goods are: (i) reasonably suitable for the purposes for which these are generally intended; (ii) in good working order, free from defects; and (iii) usable and durable for a reasonable period of time.¹⁹ The consumer is also entitled to the performance of services in a manner and of a quality that persons are generally entitled to expect.²⁰ It also provides for an implied warranty in each transaction or agreement relating to the supply of goods to the consumer, and that the importer, distributor and the retailer *each warrants* that the goods comply with the requirements and standards contemplated in the CPA.²¹ These provisions applied to the health care context are obvious and extend

Melodie Slabbert is a Professor in the Department of Jurisprudence, School of Law, Unisa, and an advocate of the High Court of South Africa.

Michael Pepper is a Professor in the Unit for Advanced Studies and Extra-ordinary Professor in the Department of Immunology, Faculty of Health Sciences, University of Pretoria. He is also Professeur Associé in the Department of Genetic Medicine and Development, Faculty of Medicine, University of Geneva, Switzerland.

Corresponding author: M N Slabbert (slabmn@unisa.ac.za)

to transactions from medical treatment and procedures (including the implantation of a prosthesis) to the dispensing of medicines.

The CPA provides that the producer or importer, distributor or retailer of goods is liable for harm caused as a result of the supply of unsafe goods; a product failure, defect or hazard in goods; or insufficient instructions or warnings to the consumer relating to any hazard arising from or associated with the use of the goods, *irrespective of whether the harm is the result of negligence on the part of any of these parties*.²² This changes the legal position prior to the CPA dramatically, as previously consumers relied on contractual remedies against the manufacturer whose product caused them harm, or alternatively had to institute civil claims against the manufacturer. The consumer, had to, among others, prove fault on the part of the manufacturer. This posed a difficult hurdle, as there may not have been fault present in the production process; the manufacturer may have been difficult to identify, or the consumer may not have had insight into the production process.¹⁴ The no-fault liability introduced into consumer legislation may open the litigation floodgates. To be successful in a product liability claim in terms of the CPA, a plaintiff need only prove that the relevant goods (that were unsafe, defective, hazardous or contained inadequate instructions pertaining to a hazard) have caused harm. This provision, however, does not specifically refer to a supplier, e.g. a specialist who supplies an implant for implantation may be regarded as a 'retailer' under this provision. Although medicines differ from ordinary commodities and are not regarded as commodities of trade,²³ all medicines, including prescribed and over-the-counter medicines, are subject to the provisions of the CPA.

A supplier of services who in conjunction with performing these services also applies, supplies, installs or provides access to any goods, is regarded as a supplier of those goods to the consumer for the purpose of this strict liability provision.²⁴ Thus, in the healthcare context no-fault liability may arise in respect of a range of health practitioners who supply, provide access to, or implant prostheses or medical devices. Since the claimant can sue anyone in the supply chain and hold them liable for harm and cost, and since health professionals who delivered the care are the most easily (and usually the only) identifiable person in the supply chain, they can be held strictly liable for the cost of the damages that may follow.²⁵ This applies, for example, to defective prostheses, implants, pacemakers and medications for which a claim may be brought if damage results. This provision is to protect the consumer (patient) against defective or inferior implants, as they often have no choice but to rely on the supplier's (or health care provider's) choice of goods. If more than one person is liable in terms of this provision (which will depend on the individual facts), their liability will be jointly and severally,²⁶ which means that they may be liable individually or as a group. Consumers may decide to sue the producer, importer, distributor or retailer, or all of them (which may include the health care provider, if part of the supply chain, e.g. as 'retailer').²⁷

The type of harm covered by the no-fault liability includes death, injury or illness, or pure economic loss (e.g. loss of earnings) caused by the resultant harm.²⁸ Although the causal link between the defective goods and the harm or death that resulted must be established on a balance of probabilities, the traditional common-law obstacle of proving negligence no longer applies, which makes proving product liability much easier. The consumer still remains at risk of an adverse costs order if he or she is unsuccessful in court.²⁹

Provisions of the CPA allow for class actions, including consumer protection groups, which allows a number of claimants to institute a class action,³⁰ based on a well-defined question of fact or law. Although the CPA provides for a mechanism through which consumer complaints can be addressed by the National Consumer

Commission, National Consumer Tribunal, relevant ombud or consumer courts, the only forum with the appropriate authority to resolve a *product liability* claim will be a civil court. In addition to the removal of the fault requirement, contingency fee arrangements will facilitate product liability litigation.^{29,31} Class actions may be costly to suppliers, who will need sufficient liability insurance for such claims.

However, defences are available to those against whom no-fault liability claims are brought, e.g. no-fault liability does not apply if: (i) the unsafe feature of the product, or the hazard, failure or defect, results from compliance with any public regulation; (ii) the alleged unsafe feature, hazard, failure or defect did not exist in the goods when they were supplied to another person alleged to be liable; (iii) it is unreasonable to expect the distributor or retailer to have detected the unsafe feature, failure, defect or hazard; or (iv) the claim for damages is brought 3 years after the said death or injury occurred.³²

Conclusion

With patients as 'consumers' in terms of the CPA, doctors are within the chain that extends from manufacturer to consumer. The CPA's introduction of strict liability poses problems in the health care context. Health care providers and establishments must review their medical malpractice insurance to ensure that it includes sufficient cover for product liability (to cover the risk event, quantum of damages and legal costs pertaining to claimant and defence costs) created under the CPA. Suppliers should also seriously consider improving quality controls, and if part of a supply chain, obtain appropriate indemnities from all the other parties. Although medical defence organisations continue to assist members faced with medico-legal problems arising from clinical practice, the increased exposure of members to product liability will undoubtedly significantly influence membership fees in the medium term. Only time will tell how far-reaching the Act's influence on the health care sector will be.

1. As well as Regulations published in GG 34180 of 1 April (GN R. 293).

2. See s 3(1).

3. S 1.

4. S 5(1). The Act does not apply, among others, to transactions for the supply (or promotion) of goods or services to the State or transactions that relate to services supplied under an employment contract.

5. In terms of the policy framework, a consumer is defined as a person who purchases 'goods' or 'services'. See GN 1957 in GG 26774 of 9 September 2004, par 25.

6. Ss 8-10.

7. Ss 11-12.

8. Ss 13-21.

9. Ss 22-28.

10. Ss 29-39.

11. Ss 40-47.

12. Ss 48-52.

13. Ss 53-61.

14. Ss 62-27. See also Jacobs W, Stoop PN, Van Niekerk R. Fundamental consumer rights under the Consumer Protection Act 68 of 2008: A critical overview and analysis. Potchefstroom Electronic Law Journal 2010;13(3). <http://www.scielo.org.za/pdf/pej/v13n3/v13n3a09.pdf> (accessed 20 June 2011).

15. S 4(4).

16. Excluding advice or intermediary services in terms of the Financial Advisory and Intermediary Services Act No. 37 of 2002 (FAIS), the Long-Term Insurance Act No. 52 of 1998, and the Short-Term Insurance Act No. 53 of 1998.

17. S 5(2)(b). This amount has been set at R2 million by the Minister of Trade and Industry in GG 34181 of 1 April 2011.

18. S 5(3). The Southern African Medical Device Industry Association (SAMED), for example, applied for exemption to the Director-General of Health in October 2010. See <http://www.samed.org.za/uploads/SAMED%20Submission%20to%20NDOH%20re%20CPA%20Oct%202010.pdf> (accessed 28 June 2011).

19. S 54(1)(c), read together with s 55(2).

20. S 54(1)(b).

21. S 56(1).

22. S 61.

23. E.g. the technical qualities of medicines are difficult to assess and medicines are inherently unsafe, to name but two. The Medicines and Related Substances Control Act No. 101 of 1965, amended by Act No. 72 of 2008, regulates the registration and control of medicines and scheduled substances.

24. S 61(2).

25. Howarth G, Davidow R. Don't be consumed by new Act. MPS Casebook 2010;18(3):12-13 at 12.

26. S 61(3).

27. See Slabbert MN. Medical law – South Africa. In: Blanpain R, ed. International Encyclopaedia of Laws. Alphen aan den Rijn, Netherlands: Wolters Kluwer: 2011:par 178.

28. S 61(5).

29. See Dinnie D. In a different class: Litigation and product liability. <http://www.insurancegateway.co.za/9.8.45.Irn=3043> (accessed 29 June 2011).

30. S 4(1)(c).

31. See s 2 of the Contingency Fees Act No. 66 of 1997.

32. S 61(4).