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Product recalls in South Africa

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Product recalls in South Africa and globally have attracted much attention recently. In 2021, Phillips issued a global voluntary recall in respect of certain of its sleep apnoea machines. The machines include a foam component that, when broken down, has the propensity to cause harm to consumers using the machines, including cancer and respiratory problems.

By August 2022, Philips was almost halfway through its recall of 5.5 million machines in the United States.

This recall has significantly diminished Philips' market share by an estimated $30 billion (see T Sterling et al in "FDA says faulty Philips device reports accelerating as CEO departs" in *Reuters* (17 August 2022).

Another recall that received significant attention earlier this year, was the voluntary recall of certain batches of infant formulas produced by Abbott Laboratories-Nutrition. The recall arose due to possible bacterial contamination at one of the production sites in the United States.

This recall affected consumers in more than 50 countries, including South Africa. Locally, the National Consumer Commission ("the NCC"), which is the regulatory body responsible for consumer matters in South Africa, released a media statement on 22 February 2022 urging South African consumers to return the affected formula to points of sale for a full refund.

As the above examples show, product recalls inevitably involve serious issues, including consumer welfare and manufacturer reputation and liability. It is therefore important for manufacturers, consumers and all the stakeholders between them (including suppliers and distributors) to take note of their legal rights and obligations in respect of product recall in South Africa. The focus of this article is product recalls under the Consumer Protection Act No. 68 of 2008 ("the CPA").

Legal framework

Recalls are regulated in South Africa primarily by the CPA. The CPA applies generally to goods supplied to consumers. Goods are, in turn, broadly defined in the CPA as including anything marketed for human consumption or any other tangible product. Although not the focus of this article, the recall of certain specific products is regulated more directly in sector-specific legislation.

In these circumstances, the product recall requirements of specific legislation, will in the main, take precedence over the requirements of the CPA (being the legislation of general application).

For example, the recall of medicines, medical devices (which would include sleep apnoea machines) and *in vitro* diagnostic medical devices is specifically regulated under the Medicines and Related Substances Act No. 101 of 1965. In this article, however, our focus is on the general requirements of a recall in terms of the CPA.

Recalls, harm and liability

In general, the CPA allows for two categories of recalls, namely voluntary and mandatory. Voluntary recalls are undertaken by suppliers who have proactively identified a risk of potential harm posed to consumers by the suppliers' products and who wish to manage that risk (and the supplier's potential liability to consumers) by recalling those products.

Mandatory recalls, on the other hand, are recalls which are required by the NCC where reasonable grounds exist to believe that any particular goods may be unsafe, or that there is a potential risk to the public from the continued use of or exposure to the goods (section 60(2) of the CPA).

In practice, however, most recalls are voluntarily initiated, given that the supplier has intimate knowledge of its product and the consumer market that uses those products. In this regard, voluntary recalls are based on the proactive management of a supplier's potential risk and liability.

In this regard, section 61 of the CPA creates strict liability for producers, importers, distributors and retailers of goods where harm is caused by goods that are "unsafe", suffer from a "product failure, defect or hazard" or where goods were not accompanied by appropriate instructions or warnings. Definitions for the aforementioned terms appear in the CPA as follows –

- "defect" is defined as –
  "(i) any material imperfection in the manufacture of the goods or components, or in performance of the services, that renders the goods or results of the service less acceptable than persons generally would be reasonably entitled to expect in the circumstances; or

  (ii) any characteristic of the goods or components that renders the goods or components less useful, practicable or safe than persons generally would be reasonably entitled to expect in the circumstances";
- "failure" is defined as "the inability of the goods to perform in the intended manner or to the intended effect";
- "hazard" is defined as "a characteristic that –
  "(i) has been intended as, or declared to be, a hazard in terms of any other law;

  (ii) presents a significant risk of personal injury to any person, or damage to property, when the goods are utilised"; and
- "unsafe" means "that, due to a characteristic, failure, defect or hazard, particular goods present an extreme risk of personal injury or property damage to the consumer or to other persons".

The specific types or categories of harm for which a supplier may be held liable pursuant to section 61 of the CPA, include, according to section 61(5) –

- the death of, or injury to, any natural person;
- an illness of any natural person;
- any loss of, or physical damage to, any property, irrespective of whether it is movable or immovable; and
- any economic loss that results from harm referred to above.

The provisions of section 61 of the CPA are, therefore, very broad in nature and are intended to afford consumers as much protection as possible in respect of circumstances where harm has been caused by the use of certain goods.

Voluntary product recall

Guidance on the voluntary recall process has been published by the NCC in terms of the CPA under GN490 in GG 35434 on 13 June 2012 ("the Guidelines").

A summary of the procedural requirements which a supplier must follow pursuant to a voluntary product recall is set out below –

Conduct a risk analysis of the safety hazard
According to the Guidelines, once a supplier becomes aware of a "possible safety hazard" in a product that may cause injury, the supplier is required to gather and assess all available information about the potential hazard, identify how the problem occurred and conduct a comprehensive risk analysis.

Cease production or modify the manufacturing process for the product that has been identified for recall
A supplier must then stop the production of a product that is subject to recall, alternatively, modify the manufacturing process to remove the hazard.

Notify the relevant regulator/s and relevant parties
In terms of the Guidelines, suppliers are required to notify the NCC and other suppliers in the supply chain, including international suppliers, that the recall has been has initiated. According to the Guidelines, the supplier must notify the NCC of the recall, in writing and in terms of a prescribed form, preferably before commencing the recall action, alternatively, within two days after commencing the recall action.

Determine a course of action
The Guidelines specify that a supplier must decide on the most appropriate course of action in order to reduce the risk of harm to consumers taking into account the nature of the risk, the distribution and lifecycle of a defective product. The supplier is also obliged to consult with the NCC about the most appropriate strategy for the recall.

Preparing a written recall strategy/plan

A supplier must submit a recall strategy to the NCC initiating a recall to assure the NCC that any product safety risk will be effectively mitigated. The recall strategy must contain specific information, including an explanation of the problem, the number of products affected, the hazards associated with the product and the supplier's assessment of the risk posed by the product.

Communication plan for consumers

In addition to the requirement of the submission of a recall strategy, the Guidelines require a supplier to compile a communication plan and recall notice for its consumers which must be "directed towards the particular consumer demographic for the recalled product, using an appropriate communication method". The recall notice must include a clear description of the product and the defect (including a photograph of the product).

The communication must also include a section entitled "What To Do", which explains the immediate *action* the consumer is to take, for example, cease use immediately and return the product to the place of purchase for a full refund. It should be clear that the consumer should return the product and not dispose of the product. The supplier must also minimise any inconvenience to consumers and encourage consumers to comply with the recall notice. Finally, the communication must include the relevant contact details for the persons responsible for the recall.

Arrangements for the retrieval

The Guidelines prescribe that suppliers must make arrangements for the actual retrieval of the recalled product.

Reporting obligations

Finally, significant reporting requirements are also prescribed in the Guidelines for suppliers who undertake the recall process. In particular, the Guidelines provide that "[i]n order to monitor the progress and enable ongoing assessment of the effectiveness of the recall the [NCC] requires a supplier to provide progress reports".

The NCC will also develop a reporting schedule with a supplier at the beginning of a recall that appropriately reflects the product risk being addressed.

The information that the NCC will require as part of any progress reports will be dependent on the circumstances of the recall and therefore will be negotiated on a case-by-case basis. Information that may be required by the NCC in terms of the progress reports includes the number of products returned from within the supply chain and those from consumers.

Conclusion

Ultimately, therefore, whilst the NCC may elect to pursue mandatory product recalls in certain instances, the publication by the NCC of the Guidelines has emphasised, firstly, the responsibility that suppliers bear in being proactive in monitoring and ensuring the continued safety of products sold to consumers and secondly, the need for suppliers to take sufficient and expeditious voluntary steps to mitigate any safety concerns apprehended in respect of those defective products.

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