

THE PIASA BRIEFS: THE NEW CONSUMER PROTECTION ACT

Implications for the consumers of medical scheme products and services

This brief forms part of a series developed by the Pharmaceutical Industry Association of South Africa (PIASA) in the interest of patient education. It explores specific implications of this new Act for the medical scheme sector, current and future members (who are all customers in terms of the law), and agents, such as brokers and administrators. The views expressed in this brief do not constitute legal opinion or legal advice, and consumers should seek assistance to take any matter further.

The right to fair value, good quality and safety

The new Consumer Protection Act (CPA) includes a number of key fundamental consumer rights. The Act will come into force in the near future.

This right includes, amongst others, the following:

- Knowing what a “defect”, “failure”, “hazard” and “unsafe” services or goods are.
- The consumer’s rights to demand quality service.
- The consumer’s rights to safe, good quality goods.
- The right of an implied warranty of quality.
- The right to receive warning concerning any risks.
- The recovery and safe disposal of designated products or components, safety monitoring and recall
- The supplier’s liability for damage caused by goods

Right to quality service

Section 54 of the CPA awards you the right to:

- The timely performance and completion of services, and the timely notice of any unavoidable delay thereof, for example if pre-authorisation is promised within 48 hours, the pre-authorisation has to be delivered within 48 hours.
- The performance of the services in a manner you expect and of a quality you expect. This also means that where the scheme contracts others to provide call centre services, managed care services or even health services, they have to ensure that such contractors’ performance is good.
- Expect that the services and products recommended by the scheme, for example, are free of defects and of expected quality.

Consumers have a right to either a remedy of the service or goods (i.e. that it would be supplied as it should have been, or the right to a refund, taking into account the extent of any failure).

Right to safe, good quality goods

Section 55 awards every consumer has a right to receive goods that:

- Are reasonably suitable for the purposes for which they are generally intended, e.g. a consultation with a medical practitioner and medication paid for by the scheme should have its intended purpose, i.e. to manage the patient (member’s) condition in return for a fee in the form of a premium.
- Are of good quality, in good working order and free of any defects.
- Will be useable and durable for a reasonable period of time, bearing in mind its use, such as a new hip that is transplanted, which you would expect to be lasting for a significant period.
- Comply with any applicable standards set under the Standards Act, 1993 or any other public regulation, such as the requirements set for medicines under the Medicines and Related Substances Act.

If a consumer has specifically informed the supplier of the particular purpose/use for which s/he wanted the goods (e.g. to manage their high blood pressure or high cholesterol), the consumer has a right to expect that the goods are reasonably suitable for that purpose. In evaluating the suitability of goods, its marketing, packaging and display will be considered, as well as the instructions, warning, etc. that is provided with it.

Implied warranty of quality

Section 56 states that there is an implied warranty with all goods relating to:

- The right to return goods within six months after the delivery of the goods if the goods failed to be reasonable suitable for its purpose, were not of good quality, or not in compliance with standards set.
- The right to return repaired goods if within three months after that repair, the failure, defect or unsafe feature has not been corrected, or another failure, defect or unsafe feature appears.

In both the cases the supplier must either refund the consumer the price paid for the goods or replace the goods. It should be borne in mind that in some cases, other laws prohibit the return of goods, such as opened medication. In some cases products cannot be returned (such as an implant), but there may be a right to receive a refund.

Warning of risks

If there is:

- any unusual risk, or
- a risk that a consumer could not reasonably be expected to be aware, or
- a risk that could result in serious injury or death,

the supplier must specifically draw that fact to the attention of the consumer.

Certain types of treatment covered by medical schemes carry a risk inherent in such treatment. Examples are chemotherapy, or operations where anaesthetics are used. And in comparing one type of healthcare intervention with another (which is what managed care does, and then recommending one over another), the risks have to be explained to the member (patient).

Both packaging and instructions should comply with published standards and should provide the consumer with sufficient instructions on the safe handling and use of the products. With medicine, the instructions are found on the pack and inside the package in the leaflet or insert. With equipment, an instruction manual is often provided. If a professional uses the goods, s/he has to make sure they do it correctly and in line with the instructions.

Recovery and disposal

Section 59 covers cases where goods may not be thrown into the "normal" waste collection system, such as medicine and medical waste. The CPA places a duty on the supplier to ensure that goods are disposed of in terms of applicable regulation or an industry waste management plan.

Safety monitoring and recall

The Consumer Commission must work towards the development, adoption and application of industry-wide codes relating to consumers:

- reporting or complaining about product failures, defects or hazards;
- returning goods because of a failure, defect or hazard;

- suffering personal injury, illness or damage to property caused wholly or partially as a result of a product failure, defect or hazard.

A monitoring system already exists for medicine through the Medicines Control Council and the structures and processes it has. One should also be in place for medical devices soon.

Liability for damage or harm caused

Section 61 creates a system where you could hold everyone in the supply chain who participated in you getting a product, liable for the harm it caused.

The liability could be found if suppliers provide you with:

- unsafe goods (i.e. goods that should not have been provided due to the risk it places on someone);
- a product failure, defect or hazard in any goods; or
- inadequate instructions or warnings

The CPA contains definitions of what is meant by safety, defects, etc:

- A "defect" refers to material imperfections that comes from the manufacturing of something. It can also refer to a lack of good performance in providing services, i.e. the service is worse than what you would expect.
- A "failure" means if the goods does not perform as it should be performing.
- A "hazard" is something that forms part of a product and that presents a significant risk to you or your property. All equipment that uses electricity, for example, pose a hazard.
- If something is "unsafe", it means that a part or something in a product pose an extreme risk of personal injury or property damage to you or others. Hazards can be managed, whereas unsafe goods may be regarded as presenting too much of a risk to even be used at all.

However, if the failure, defect or hazard did not exist when goods were supplied to you, or where you did not follow the instructions supplied (such as taking the medicine in a particular way, or going back to your doctor if the wound did not heal properly), you will be able to hold the suppliers liable.

Liability in terms of this provision may be shared between suppliers (i.e. your medical scheme, a hospital, pharmacy, doctor, etc).

Claims have to be made within three years after the harm occurred.

Examples

In terms of this right, consumers who are members of medical schemes should be able to expect services within stipulated times. You also have the right to expect that the product (such as a medicine) recommended by their schemes (in the form of medicine lists or equipment lists or as preferred suppliers) would be of the quality and fulfill the requirements it is expected to.

Similarly, a medical scheme or medical scheme plan recommended by a broker should fulfill the needs as expressed by the consumer when buying it. It is therefore important that, when buying medical scheme cover, the level of service and cover are made clear, as well as the implications of this.

A medical scheme option that offers care on the basis of capitation (i.e. they only pay the doctor a fixed fee irrespective of how often the member visits the doctor or what the costs of the visits are) has to be explained as having the impact of limiting the range of treatment options available to you. The same principle will apply where certain services may only be obtained from certain designated providers (pharmacies, doctors, hospitals, etc).

Consumers also have to make clear what their healthcare requirements are, when interacting with brokers. If you have communicated this clearly, the broker would have to make sure that what is offered to you, actually reasonably fulfill those needs (i.e. is "purposeful").

Where treatment choices are limited by means of managed care criteria, such as limited medicine lists, or monetary caps being placed on treatment, beneficiaries should be warned about any risks they may be taking in accepting such recommendations. Of particular concern may be the use of treatments for purposes other than it was registered for (i.e. so-called "off-label use" of a product), as such risks would be "unusual" within the context of the CPA.

This right also affects the providers of health services and products, such as pharmacists and doctors. If a service is provided that leads to harm, and the medical scheme recommended the treatment, the scheme could share the liability with the providers. You should therefore be informed, as a consumer of the following:

- The purpose of the specific treatment and what it is intended for;
- The risks associated with it;
- Instructions on the use of treatment or what you should do whilst on treatment, or after treatment; and
- What to do if you experience any negative effects as a result of treatment, or if the treatment fails.

The Pharmaceutical Industry Association of SA (PIASA) is a trade association of companies involved in the manufacture and/or marketing of medicines in South Africa. The membership includes a broad representation of foreign multinational pharmaceutical companies and local and generic companies, both large and small.