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PRICE CRISIS

Can competition law fix SA's drug (price) PROBLEM?

Along with cancer medicines being probed comes the call for companies to account for the costs incurred

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Just because medicine prices are regulated, does not mean they are fair or competitive.

The investigation into the pricing of cancer drugs, announced by the Competition Commission this week, has been met by an industry retort that drug prices are already regulated under the single exit price (SEP) system, meaning industry players cannot abuse pricing.

Speaking to City Press this week, Competition Commission head Tembinkosi Bonakele dismissed the apparent contradiction.

None of the three large pharmaceuticals being probed - Aspen, Swiss multinational Roche and US giant Pfizer - is alleged to have contravened the SEP system, but even a price lower than the regulated maximum can be "excessive" under competition law, he told City Press.

"We have investigated other sectors before, regardless of price regulation, such as telecommunications," he said.

All medicines marketed in South Africa are subjected to a national maximum price that gets adjusted for inflation annually by the department of health.

However, activists and academics have pointed out for a long time that this system has a weakness: the initial price of a drug is set almost entirely at the discretion of the company selling it.

If a drug has no competition - thanks to patent regulation or the minute size of the market for a rare treatment - a company can set a regulated price as high as it wants.

"The initial SEP is at the discretion of the manufacturer or importer and is entirely based on their own commercial calculation, relative to possible competitors," said Andy Gray, senior lecturer at the University of KwaZulu-Natal's School of Health Sciences and a research associate at the Centre for the Aids Programme of Research in SA.

"There is no accounting for any costs incurred, whether in development, in manufacture or in marketing, and such costs are confidential," said Gray.

The whole point of this system is to have only one price for private sector buyers - not to have a cost-reflective or fair price.

Civil society groups such as the Treatment Action Campaign (TAC) and Section 27, which helped bring at least one of the three cancer drugs in question to the Competition Commission's attention, have long doubted the SEP system.

"The TAC and Section 27 do not support the current system by which the initial SEP is completely discretionary and untransparent - and whereby prices can be set at levels unaffordable to most of the population," Section 27 told City Press via email.

The groups have called for the SEP system to incorporate reference pricing. This entails comparing the price set by companies to prices in other countries before sanctioning it locally.

Gray said a proposed system for this kind of international benchmarking was published years ago, but went nowhere.

Another option is doing a "pharma economic analysis" of the price, which means comparing the value of one pharmaceutical drug or drug therapy to another. South Africa has guidelines for this, but it is voluntary and has not yet been used to challenge a medicine price, said Gray.

IT HAS WORKED BEFORE

Competition law has been used to achieve massive gains for health activists in the past.

In 2003, the TAC and the Aids Law Project - the precursor to Section 27 - reported three overpriced antiretroviral medicines to the commission. The case was referred to the Competition Tribunal, which led to the pharmaceuticals involved settling in a deal that saw generic manufacturers receive licences to produce the drugs.

"The voluntary licences led to generic competition and much reduced prices which, in turn, helped facilitate the large-scale rollout of antiretrovirals in South Africa," said Section 27.

Despite this, the organisation "felt that fighting on a case-by-case basis at the Competition Commission was not sustainable, given our limited resources".

Instead, it has become part of the Fix The Patent Laws coalition, which is lobbying for generics-friendly reform.

"As it stands, though, people are dying because they cannot afford certain medicines, so we will use whatever law is available," said Section 27.

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THE PRIME SUSPECTS

Roche, Aspen Pharmacare and Pfizer are under investigation for their respective excesses displayed in pricing their cancer drugs

1 Roche: Keeping out generics

The most severe and specific case being made by the Competition Commission is against Swiss multinational Roche around Trastuzumab, a breast cancer drug sold under the names Herceptin and Herclon.

It echoes the allegations made by the Tobeka Daki Campaign for Access to Trastuzumab, launched by Section 27 and other groups in February. The campaign is named in honour of activist Tobeka Daki, who died of breast cancer last year.

This investigation had "multiple trigger points", said Competition Commission head Tembinkosi Bonakele.

The allegation is that Roche and Genentech, the actual patent owner for which Roche markets the drug, are abusing patent laws to stop generic versions from becoming available, and then charging excessive prices.

Roche would not comment, but in February, the company responded to local campaigners by saying it would "not necessarily" stop so-called biosimilar (generic) versions of the drug being produced.

At the same time, Roche has been slated for its aggressive litigation against generic versions of its drug elsewhere in the world.

2 Aspen Pharmacare: Gouging

The allegations against Aspen largely repeat those in an investigation announced three weeks ago by the European Commission, which accuses Aspen of "price gouging" by hiking the prices of niche cancer medicines by several hundred percent after acquiring them from GlaxoSmithKline.

These are off-patent drugs that have very small markets, which has meant that they have garnered little attention from generic competition.

Bonakele said that while the European case influenced the commission, it had been looking into the pharmaceutical companies for a while.

"We have been doing our own stuff for over a year, even before the European Commission raised these issues," he said.

Aspen responded by saying it had never increased prices beyond what the SEP system permitted.

3 Pfizer: Mistaken identity?

The primary allegation against Pfizer may be based on a case of mistaken identity.

The commission said an "agent" for Pfizer charged R152 000 for a 250mg dose of unregistered cancer medication Xalkori Crizotinib.

"When the price was queried, this agent halved the price," said Bonakele.

This raised a red flag, but the agent in question said it had nothing to do with Pfizer.

Benjamin Miny, managing director of Equity Pharma Holdings, told City Press that his company procured unregistered medicines for patients in South Africa using special import permits under section 21 of the Medicines and Related Substances Control Act.

Equity Pharma had imported very small amounts, he said.

Miny said the price of the drug had been dramatically reduced in South Africa because Pfizer had started to supply it in the country itself.

"Since then, we have referred everyone to them."

Miny defended his company's pricing, saying the drugs were imported from the EU when the rand was far weaker.

Bonakele said: "There are other grounds for that investigation. The halving of the price is only one of them."