

Price gouging is not in Aspen's DNA, says founder Stephen Saad, incensed at the thought that his company would exploit the sick. But Aspen's predicament, and that of all drug firms, boils down to the tension between a drug company's perceived responsibility to provide life-saving drugs to patients at a reasonable price, and its natural objective to turn a profit

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tephen Saad's frustration at Aspen being branded a "price gouger" that drove up the cost of life-saving medicine for profit is palpable. In an interview with the Financial Mail, the 53-year-old says Aspen Pharmacare has been the victim of a "perfect storm" that has led to his company being unfairly cast as a villain.

"That was probably the most disappointing part: you've got a company that loves SA, has created thousands of jobs, loves what it does, provided antiretrovirals that many people rely on and created a huge saving for government – and the media turned on us." he savs. Ripping people off, he says, just isn't in Aspen's DNA.

Saad has had perhaps his toughest two months since he and Gus Attridge founded Aspen 20 years ago in a small house in Greyville, Durban, and became the dazzling success story of SA entrepreneurship in the new millennium.

From a company with R123m in revenue, Aspen now clocks up R35bn. It makes pharmaceuticals at 26 facilities on six continents, exports to over 150 countries and produces more than 700 tablets a

Investors became fabulously rich. People who put R10,000 into Saad's company in 1997 would have made R5.6m including dividends

But now Aspen is facing its most serious skirmish yet.

In April, accusations of price gouging in Europe rocked Aspen, as The Times of London splashed the story "drug giant's secret plan to destroy cancer medicine" across its pages. The Times said the cost of busulfan, used by leukaemia patients, spiked from £5.20 to £65.22 in 2013, while chlorambucil, a chemotherapy medication, rose from £8.36 to £40.51 a pack.

> Then, last week, the competition commission of SA decided to launch its own probe into three oncology drugs, which Aspen bought in 2009 from pharmaceutical giant GlaxoSmithKline (GSK).

All the drama has weighed on Aspen's share price, which is down 1.3% since

the revelations first broke – a loss of RI.7bn in market value – and compounding its slide over the past year, down 22.9%

But Saad is adamant Aspen has done nothing wrong. In Italy, he says, the €5.2m fine for hiking cancer drug prices by between 300% and 1,500% was particularly iniquitous. Aspen appealed to the Italian courts but lost last week. Saad says the price rises were fully justified as they hadn't risen for over 40 years. "Is it fair to ask a company to charge you today what they charged in 1950?"

And he is exasperated by the Italians' approval of a generic version of those drugs, produced by a rival, at more than double Aspen's price.

"When people think about price gouging, they think about products (in the US) that went to \$800 a tablet from \$1. From an Aspen perspective we've been very clear: we're talking about a small portfolio in the Aspen world at €2 per tablet. You can't buy a bottle of water for €2. In absolute terms no-one can call you a gouger at €2 a tablet."

The SA case is even more curious.

The competition commission's intention to tackle Aspen felt a bit as if the regulator had simply hitched a ride on Italy's coat-tails, not wanting to miss out on a potential fine for anti-competitive behaviour.

Saad says what makes it odd is that Aspen is suspected of "excessive pricing" of its cancer drugs, yet drug prices are controlled locally by the single exit pricing (SEP) rules, which means companies don't have much leeway to rip off customers even if they want to do so.

"Everything is public," he says. "The whole SEP is on a website. You could easily have looked at that pricing and maybe had a chat to us."

But this reasoning cuts no ice with the commission, which points to recent alarming hikes in medicine prices.

Hardin Ratshisusu, the deputy commissioner in charge of the probe into Aspen, Roche and Pfizer, says "the onus is on them to explain what informs those steep price increases".

Just because there's a medicine regulator doesn't mean the market is necessarily competitive, he adds. "Port charges, for instance, in SA are regulated but the outcome points to the possibility that there could be overcharging in some segments. In this particular case, there is clear information that there is possible exploitation," he says.

To some extent, the commission seems to be looking for a magic potion to deal with the nasty consequences of a globalised free market.

The commission laments the fact that Aspen "appears to be the only supplier of a generic version of busulfan in tablet form. No other products containing the same active ingredient appear to have been registered by the Medicines Control Council (MCC)."

But this is because the weakening rand, as well as regulations, hardly encourage multinational drug companies to enter SA.

cover story / aspen

Ouite what the commission can do about the ebbs and flows of the global pharmaceutical market is anyone's guess.

Saad is incensed by the view that Aspen has profited at its customers' cost.

"You can see it in our numbers - costs are going up higher than sale prices," he says. So while Aspen's profits might still be rising, it is absorbing higher costs: hence its earnings margin fell from 27.1% in 2010 to 25% now.

Even Aspen's rivals are taken aback by the attacks on the company. Ascendis Health CEO Karsten Wellner says: "Life (among) investors goes in cycles. Aspen was the darling for many years. Same as Valeant, which was the darling at the Jefferies [international health-care] conference and a year later was the fallen hero."

Wellner says Aspen has "some problems but it's still a fantastic success story. It's not insane what they're doing compared to some originators."

But Aspen's standoff with various governments seems less about the value in question its European oncology portfolio accounted for €60m in sales last year, or 3% of Aspen's overall sales – and more about global politics.

In a world where populist rhetoric has swung elections in the US and the UK, politicians are quick to seize on any profit made by drug companies as immoral.

In a recent research report, JPMorgan analysts warned state health-care systems around the globe are facing a cash crunch – and cutting the prices of medicine is always going to be an easier sell than slashing nurses' salaries.

As an example, when the patent expired on anti-cholesterol drug Lipitor, the UK's national health service saved "more than the SA government spends on drugs in total outside the state antiretroviral tender," says JPMorgan.

So in this context, the competition authorities achieve with just can be the blunt tools of governments eager to explain to citizens why medical costs are rising.

Of course, it hasn't helped drug firms that there have been clear cases of price gouging. The villain of the piece has been Martin Shkreli, the 34-year-old co-founder of hedge fund MSMB Capital Management and former CEO of Turing Pharmaceuticals.

Shkreli earned the moniker "most hated man in America" and "pharma bro" after his company bought the manufacturing licence for antiparasitic drug Daraprim in 2015, and overnight hiked the price from \$13.50 to \$750/tablet. As the Financial Times pointed out, Daraprim was discovered decades ago and is available in developing countries for a few cents. Shkreli was arrested and charged with fraud – not for price gouging but for defrauding investors in two, now defunct, hedge funds.

These practices were slated by both Hillary Clinton and Donald Trump in the US, the world's most lucrative pharmaceutical market. But price regulation is probably a pipe dream as Trump's legislative fumbles mount.

Surprisingly, Saad is in favour of regulating SA's pharmaceutical market, provided it's done fairly. "The US is a very complex system, a lot of people have vested interests and are all taking a cut. In SA, vou had similar rights, vou were in control of your prices, and the only thing really that kept your price down was competitive pressure, which I fully believed in. But then there was lots of (cost) pressure on the healthcare industry and the SA authorities brought in the SEP, which I was dead against," he says.

While Saad initially protested at single exit pricing, he has since changed his mind and now deems it a "very efficient" model.

"From an Aspen perspective, it was an absolute dream. Now it's so simple. What you can

giving inflationary increases is that your medicine bill as a percentage doesn't increase as such a big portion of your overall cost. It's transparent, and it's actually a model which could be exported to the rest of the world," he says.

Aspen's predicament, and that of all drug firms, boils down to this: the tension between a drug company's perceived responsibility to provide life-saving drugs to patients at a reasonable price, and the obvious need for the company to make a profit

To understand this, you need to understand the pecking order. At the top are the "originators" who spend billions developing new medication. They then charge to recover these costs.

Graeme Korner of fund manager Korner Perspective describes the "big pharma" firms such as Pfizer and Roche as the "big oil tankers" that have to stay in the main tanker channels. "When Pfizer comes out with a blockbuster (drug) it can be a game changer but there is a lot of money being spent on R&D that is not going to generate returns."

The next layer down consists of generic companies like Aspen, which scoop up drug portfolios of patents that have expired, or which aren't considered moneyspinners by their original owners. They use their distribution networks to extend the profit lifespan for these drugs.

Korner describes these portfolios as "cigar butts" – stubby but with some puff. Saad says these products are still relevant but can fade from the market if people don't invest in them because the margins are small. "If we can do a million across 50 countries it's worth something to us," he says.



"Doctors tend to love originators," says Wellner, but legally every pharmacist in SA must offer a generic alternative.

But getting a return on this investment has become the most politically contentious issue for the pharmaceutical industry, which increasingly finds itself at loggerheads with government's efforts to rein in ballooning health-

Speaking to the Financial Times last year, Brent Saunders, CEO of Botox maker Allergan, warned that pharma companies could no longer afford to continue with "toxic" pricing policies. "We shouldn't make the mistake of believing (the newly elected Republican party) will allow egregious behaviour to continue ... I think if we self-regulate and stop doing these big doubledigit price increases, we will be in a much stronger position."

But generic manufacturers like Aspen aren't slapping on double-digit increases.

Saad says pharma companies can balance investors' desire for profit with a consumer's right to fairly priced medicine. "We demonstrated that for nearly 20 years. But you can see that our business has been very volume-driven rather than price-driven."

It's far harder for research companies, says Saad. "When they don't get it right, no-one wants to compensate them, and when they do get it right they've got to be careful how they price. It's easy for me to be moralistic but I think (Aspen) is in quite a sweet spot: we are not a research-based company and we're not a commodity-generic company, so we try to find

niche or difficult manufacturing." Globally, generics are still a strong business. While over-thecounter (OTC) medicine is growing at 8%-10%/year, for generic medicine it is 4%-8%, and the originators aren't growing at

But, Wellner warns, "vou constantly have to feed (a generics business) with new products or you can't sustain margins as they continue to go down."

Though Aspen still makes plenty of generics in SA, they account for only 20% of its current business. Now it has gone into OTC drugs and speciality products, like infant milk, anaesthetics and anticoagulants.

Aspen is now the biggest producer of anaesthetic drugs outside the US, and the secondlargest producer of anticoagulants

"I mean this with no arrogance, but sometimes I have to pinch myself – are we really this?" says Saad. "We've really tried to evolve the business into areas which are niche, which have a future, areas which are not easily replicable."

Saad describes SA as the "foundation" of Aspen's global empire, while cutting its teeth in emerging markets has helped build the business into a global player. "What we learnt was that government isn't always the only player. A lot of people pay out-of-pocket and so if you put something on the shelf that's too expensive and people can't afford it, they can't use it."

So, for example, Aspen took a branded medication from one of the multinationals and made a generic version which it sold for 30% below the price of the original. "We got more absolute profit than the branded product ever had. That's been our model and we put that out onto a global stage," he says.

Saad seems to be taking it all rather personally, which is perhaps understandable, given that he's still Aspen's largest shareholder, with 12.1% of the company, worth R15.3bn at last

Mercifully, the fallout from other shareholders has been limited. "The story broke two months ago and the share's gone nowhere," Saad says. "Is there a shareholder fallout? Not

that I've seen. Is there a media fallout? Yes. What compounded the media fallout is the issue of sub judice where you can't say too much so anybody can hurl a stone at vou."

Still, going from celebrated entrepreneur to media pariah has been a bitter pill. "To be hon-

est, I never wanted to be listed, I never wanted to be high-profile," he says. "I just love doing what I do and if I could do it unlisted I'd do it tomorrow. To be listed is a means to an end."

But the reality is that it's not just the past couple of months that have been rocky. The stock has been on a steady decline ever since GSK – once regarded by some in the market as a potential suitor for the whole of Aspen began selling its 19% stake in the company from 2015. With hindsight, GSK got a good price, cashing in its last 6.2% tranche at R300/share in a slightly discounted bookbuild.

While this is some distance off Aspen's high of R448, it's still above the R276 level at the time of going to print.

However, analysts carp about disclosure – a view strengthened by the fact that Aspen did not disclose the European fine until it was in the news. This is why Aeon Investment Management head Asief Mohamed observed that the real issue wasn't the fine itself but "the potential damage to Aspen's reputation" in the way it handled the issue.

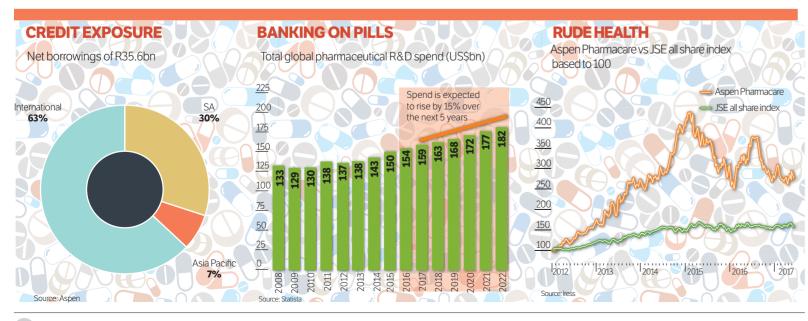
Analysts say Aspen must sharpen its disclosure. For example, it ought to distinguish between what part of its growth is due to acquisitions and what part comes from organic sales. JPMorgan adds: "A lack of product disclosure is also frustrating. While the acquired anaesthetics portfolios appear to have got off to a solid start, it's too early to have much confidence in the trajectory of future revenues and we question whether disclosure will enable accurate tracking"

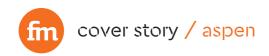
It complains also that Aspen's management makes only two results presentations a year, a limited interaction with investors.

Saad responds: "I'm a shareholder and your best bet for your money is to let us do what we do best, which is to run our business. We're not professional managers in the sense that I'm going to try to impress a whole audience at a conference in London or New York."

He says there's only so much time in the day he can devote to one-on-ones. "Unfortunately one of the issues with Aspen is because it started so small, people have open access and as it gets a bit bigger, everyone expects the same."

"Price fixing" scandal aside, has Aspen





Big bilking pharma

It's tempting to view Big Pharma as Dr Evil in the medical value chain, but the resources that are ploughed into developing "blockbuster medicines", without certainty of success, are colossal. According to PhRMA, which represents pharmaceutical research companies in the US, it takes on average 10 years and US\$2.6bn to develop a new medicine, with only 12% of candidates in clinical testing ever making it to the market. PhRMA says in the past 16 years "there were more than 120 unsuccessful attempts to develop medicines to treat Alzheimer's disease, 96 for melanoma and 167 for lung cancer. Only four were approved to treat Alzheimer's, seven for melanoma and 10 for lung cancer".

Of course, if your firm does successfully develop a cure for the conditions that are increasingly set to befall ageing high-income nations, then you are in the pound seats. Lipitor, the anticholesterol wonder drug, for example, raked in sales of over \$9bn/year for parent Pfizer before going off patent.

Pfizer, incidentally, spent \$7.87bn on research and development (R&D) expenses in the 2016 financial year — almost three times Aspen's annual revenue at recent exchange rates.

Ascendis Health CEO Karsten Wellner says the development cost of a single new chemical entity can be as much as \$850m. For "biosimilars" officially approved versions of original products, also known as "follow-on biologics" - Wellner says the cost is about \$100m, while a commodity generic can be as low as \$1m.

Investopedia lists 10 steps to producing a new drug, including developing the compound, clinical trials, initial US Food & Drug Administration application, review, inspection and, finally, approval — or rejection.

Clearly, none of this is cheap, but Health Affairs Blog, a health policy site that has been used in US congressional testimony, says R&D costs do not explain high US drug prices in particular. Its research found there are "billions of dollars left over even after worldwide research budgets are covered".

"To put the excess revenue in perspective, lowering the magnitude of the US premium to a level where it matches global R&D expenditures across the 15 companies we assessed would have saved US patients, businesses and taxpayers approximately \$40bn in 2015." x



lost its mojo? In other words, is it still a good bet for long-term investors? The sentiment seems to suggest upside to the stock, but experts are wary, given Aspen's recent surprises. Seven of the 13 analysts who cover Aspen rate it a "buy", five say "hold" and one says "sell". On average, they expect it to hit R323.78 within a year, implying a potential return of just over 17% from its present price.

But there's a lot of caution out there. John Thompson, an analyst at Investec Asset Management, says the company has disappointed investors during the past three reporting periods, and earnings downgrades keep coming.

"The market has been too optimistic and that is a factor that has repeated itself," he says. "Currencies are not working in their favour and pricing is also not working in their favour: they were hoping for better profitability but not getting it."

Thompson is also concerned that Aspen's dealmaking frenzy of the past five years has thrown too many balls into the air. "They've talked up their ability to generate earnings and cash flow, but have failed to take into account the complexities involved in all these different businesses. Had there been only one market then it might be a little easier, but here you've got anaesthetics, anticoagulants, oncology and others," he says.

Saad's company has spoken about how it expects to create R2.5bn in "synergies" by its 2019 financial year from all the drugs it has bought in the past three years. Analysts from JPMorgan say there'll be "fewer opportunities to raise or hold pricing" which could erode Aspen's ability to hit that target.

Another issue is that Aspen's big-ticket deals have landed it with a total debt load of R35.7bn - a gearing ratio of 43% of its equity. Last year, it paid Rl.8bn just in

But Saad defends the firm's acquisitions. "I wouldn't give back any of those big transactions. There are small ones where we made mistakes with products but the really big ones are all right. What's really important for us is to settle down the anaesthetics (portfolio) and grow in China,"

Investec health-care analyst Marcelle Jankelow estimates that gearing will drop to just 25% by the 2019 financial year. But Thompson is worried that Aspen's borrowings mean it won't be able to do any new deals for the next 12 to 18 months.

If they aren't able to do any more big deals, maybe it won't be such a bad thing for investors who now want to see Aspen turn its acquisitions to account

Says Korner: "I think it's a better business now than it was five years ago, so your margin of safety is probably (higher). They don't just buy, they sold assets too, so they don't have a problem selling stuff if it doesn't make sense."

Analysts estimate Aspen's earnings would be close to R18/share, which would put it on a forward price-to-earnings ratio of about 15 - historically cheap for Aspen.

"They've reduced dependency on generics and focused on a couple of key markets. And you're paying a 15 multiple for about 20% earnings growth whereas in the past you were paying a lot more," he says.

Cash is also starting to flow back in. Asked if Aspen might ever need to go to market to raise capital, Saad says: "There is definitely no need for a rights issue as organic cash flows are more than adequate for our debt profile under present circumstances."

Saad, of course, doesn't buy the view that Aspen's glory days are behind it. "We've probably got more relevance now than we ever had because we can do what we've achieved in some of our emerging markets with our business model, across a much broader geography. To do that we had to get a global supply chain and global marketing in place," he says.

From this base, building future products isn't as costly. "We've created something we can extract value out of over the next five or 10 years."

This is why he's resisting any effort from predators to buy Aspen. "There are a lot of people who want to buy Aspen and it's quite tough because I've got to talk not as a sole shareholder, which I sometimes feel. We've done all the hard work and now we need to get the fruits of all of that hard work."

But a partner who could add value – put Aspen in a new country or expand its portfolio in another – is a discussion he's willing to have. "Would I sell now? Absolutely not, because I think there are a lot of synergies still to extract from the business, there's a lot of value to add." x