EFFECTS OF DOMINANCE ON PRICE – IS THIS ALTERING THE MARKET DYNAMICS?

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Private sector embracing universal healthcare

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Overview

- Background
- Legislative framework
- Relevant case studies
  - Napp Pharmaceutical Holdings
  - Pfizer/Flynn
  - Sasol Chemical Industries
- Impact of legislative factors on the pharmaceutical arena

BACKGROUND

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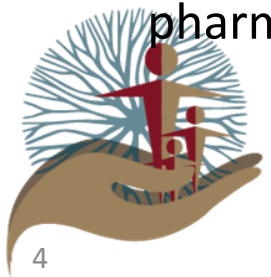
The Commission’s key performance sectors

- In its 2016/2017 Annual Performance Plan, the South African Competition Commission identified the following as key performance sectors:
- 3 cases of conduct relating to **abuses of dominance** in **prioritised sectors** should be initiated.
- Priority sectors are the strategic sectors which have been identified by the Commission in which it will focus its enforcement and advocacy work. The Commission's selection of its priority sectors to include those with high-growth and jobs potential.
- **Healthcare** (the entire value chain, including services and pharmaceuticals) is included as a priority sector.



The pharmaceutical sector – Recent investigations

- Increased focus on pharmaceutical pricing both domestically and internationally.
- Locally, the Competition Commission recently announced an investigation into manufacturers of cancer drugs, including Pfizer and Roche.
- Internationally, Pfizer is currently appealing the UK CMA's finding that it charged excessive prices and unfair prices in the UK in relation to phenytoin sodium capsules, which are used in the treatment of epilepsy to prevent and control seizures.

South African investigations: Pfizer – Alleged excessive pricing

- In June 2017, the Commission initiated an investigation against Pfizer for allegedly excessively pricing a lung cancer treatment medication, known as xalkori crizotinib. Pfizer is allegedly the only provider of xalkori crizotinib in South Africa.
- According to the Commission, it *"is in possession of information that suggests that lung cancer treatment is unaffordable in South Africa and medical aid schemes refuse to pay for the treatment. The information available to the Commission is that xalkori crizotinib cost[s] approximately R152 000.00 for 250 mg when bought through an agent, Equity (Pty) Ltd. Subsequent information suggests that there was a price reduction to R72 000.00 per month for 250 mg. This conduct is suggestive of abusive behaviour in respect of the supply of xalkori crizotinib in South Africa."*

South African investigations: Roche – Alleged excessive pricing

- The Commission also initiated an investigation against Roche Holding AG ("**Roche**") on the basis that it and its USA-based biotechnology company, Genentech Inc. ("**Genentech**") allegedly engaged, or allegedly continues to engage, in excessive pricing, price discrimination and/or exclusionary conduct relating to the provision of breast cancer medicine in South Africa. Genentech evidently provides exclusive marketing rights to Roche for Trastuzumab in South Africa. Trastuzumab is recommended as an essential medicine by the World Health Organisation and is primarily used to treat breast cancer and certain types of stomach cancer.
- According to the Commission, in South Africa, only Roche's branded versions of Trastuzumab are available and are sold under the names "Herceptin" and "Herclon".

LEGISLATIVE FRAMEWORK

Prohibition of abuses of dominance

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Dominant firms (section 7 of the Competition Act)

- The abuse of dominance provisions only apply to dominant firms.
- 45% market share – irrebuttably dominant.
- 35% market share – rebuttably presumed to be dominant.
- There is no penalty for being dominant, nor are dominant firms discouraged from competing, however, dominant firms have a “special responsibility” not to abuse their dominance.

Abuse of dominance: South African legislative framework

Relevant examples:

- **Prohibition** against **charging an excessive price to the detriment of consumers** (section 8(a) of the Competition Act);
- Excessive price means a price for a good or service, which "*bears no reasonable relation to the economic value of that good or service*".
- **General prohibition** against **exclusionary conduct** (section 8(c) of the Competition Act);
- **Specific prohibition** against **exclusionary conduct** (section 8(d) of the Competition Act):
  - E.g.: selling goods or services below their marginal or average variable cost

RELEVANT CASE STUDIES

The pharmaceutical sector

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UK: The *Napp Pharmaceutical Holdings* case

- The findings of the UK Office of Fair Trading ("**OFT**") (2001): Napp abused a dominant position in the supply of sustained-release morphine tablets in the UK.
- At the time, Napp had approximately 95% of the market for oral sustained release morphine tablets and capsules in the UK.
- Napp's market share in the community segment, i.e. patients under care of a GP, was approximately 96%.
- Napp also supplied the hospital segment of the market. Napp offered discounts (up to 90%) off the NHS list price on hospital tenders and its market share in the hospital segment was in excess of 90%.

UK: The *Napp Pharmaceutical Holdings* case

- Relevant market for purpose of the analysis was the market for sustained release tablets in the UK.
- Given Napp's market shares in excess of 90%, Napp found to be dominant.

UK: The *Napp Pharmaceutical Holdings* case

- **Arguments by Napp:**
  - Pharmaceutical companies need to earn high margins on the most successful products in order to pay for R&D of emerging products or to subsidise less successful products – argument rejected.
  - It is not dominant because medicine pricing regulation (PPRS) in the UK prevented it from abusing any dominance it might otherwise have – argument rejected.

UK: The *Napp Pharmaceutical Holdings* case

- **Findings by the OFT:**
  - Napp had abused its dominant position from 1 March 2000 by seeking to eliminate competition in the hospital sector by pricing below direct costs and selectively targeting competitors;
  - Prices charged by Napp in the community segment were excessive;
  - On average, the wholesale community price was in excess of 1000% higher than average hospital prices and that Napp earned far higher margins in the community sector than on sales of its products to the NHS;

UK: The *Napp Pharmaceutical Holdings* case

- **Findings by the Competition Appeal Tribunal on appeal:**
  - A manufacturer with an innovative product cannot demand or expect prices to remain at excessively high levels indefinitely;
  - Did not accept that after a long period, the price of a drug can credibly be defended on a "portfolio pricing" theory;
  - Rejected the argument that drug prices cannot be excessive because it is subject to the medicine pricing regulation (PPRS), *"such argument has no foundation in law or logic*".
  - The medicine pricing regulation (PPRS) is not directed to the question whether or not the price of an individual product sold in a market where there is dominance is above the competitive level – which is the essential question.

UK: The *Pfizer/Flynn Pharma* case (2016)

- The UK's Competition and Markets Authority ("**CMA**") found that Pfizer and Flynn abused their dominant positions by imposing unfair prices for phenytoin sodium capsules (trade name "epanutin", a drug primarily used to treat epilepsy), manufactured by Pfizer and distributed by Flynn.
- Pfizer sold marketing rights for a drug to Flynn, a generics sales and marketing company. Pfizer supplies Flynn at prices allegedly up to 1,600% higher than its previous prices. Flynn adds a margin taking the total price increases allegedly up to 2,600% above Pfizer's previous prices.
- CMA imposed a financial penalty of £84 million on Pfizer and £5 million on Flynn and directed them to reduce their prices.

UK: The *Pfizer/Flynn Pharma* case (2016)

- **Pfizer and Flynn's prices found to be excessive:**
  - The CMA found that Pfizer's prices for each of the four capsule strengths were excessive, because they materially exceeded Pfizer's costs plus a reasonable rate of return (same reasoning in relation to Flynn).
  - Parties sought to argue that their prices were justified by reference to the drug tariff price of tablets, which the parties claimed was sanctioned by the UK's Department of Health.
  - The CMA found that the UK's Department of Health did not have any meaningful power to regulate or limit the price it paid for tablets.
  - Phenytoin sodium capsules have been on the market for about 80 years.

UK: The *Pfizer/Flynn Pharma* case (2016)

- **Key points in decision:**
  - No reward for risk and innovation for old drugs: patent protection is there to compensate companies for running the risk and incurring the cost of innovation. Once drugs go off patent, companies can no longer rely on these risks and investments to justify high margins.
  - Inconspicuous percentage margins may still be excessive: the CMA dismissed Flynn's percentage margin based arguments and found that absolute per unit earnings and *absolute* total earnings suggested excessiveness.

UK: The *Pfizer/Flynn Pharma* case (2016)

- **Key implications:**
  - The price in itself becomes a key piece of evidence - price increases of hundreds or even thousands of percent are in themselves seen as indicative of a problem;
  - Comparisons with prices for other drugs will not help if competition regulators can rely on price cost tests to find that prices are unfair in themselves; and
  - Costs become the primary line of defence: price increases are a factual question in an *ex post* investigation: this makes cost justifications critical.

UK: The *Pfizer/Flynn Pharma* case (2016)

- **Key evidence – prices:**
  - Prior to September 2012, Pfizer's prices to wholesalers and/or pharmacies were broadly stable, as were the drug tariff prices. With effect from October 2012, drug tariff prices for the capsules increased significantly.
  - Pfizer continued to sell capsules in EU-member states, prices did not change materially.

UK: The *Pfizer/Flynn Pharma* case (2016)

- **Dominance:**
  - The CMA considers that a firm will not be in a dominant position unless it has substantial market power.
  - In assessing market power, the CMA will consider the strength of competitive constraints, including:
    - Actual competition from existing competitors;
    - Potential competition from new entrants;
    - Buyer power;
    - Economic regulation; and
    - Financial performance of the firm in question.

UK: The *Pfizer/Flynn Pharma* case (2016)

- **Dominance:**
  - The CMA found that Pfizer and Flynn are dominant in respect of Pfizer-manufactured phenytoin sodium capsules.
  - The CMA found that the relevant market includes a single product: patients represented a captive user base as they could not switch to other drugs. No competition was hence found even from bioequivalent products.
  - The EU Court of Justice has previously held in another matter that market shares in excess of 50% are, save in exceptional circumstances, evidence of the existence of a dominant position.

UK: The *Pfizer/Flynn Pharma* case (2016)

- **Pricing behaviour:**
  - The CMA found that Pfizer and Flynn's prices in the relevant period were significantly above an appropriate measure of their respective costs, plus a reasonable rate of return.
  - Assessment involves a proper degree of discretionary judgment by the decision-maker and requires an exercise of judgment.
  - Approach to costs identification makes allowance for direct and indirect cost (both variable and fixed, including administrative overheads).
  - The CMA found that Pfizer's **prices exceeded cost plus** by at least 29% for 25mg capsules, 100% for 50mg capsules, 690% for 300mg and 705% for 100mg capsules.

UK: The *Pfizer/Flynn Pharma* case (2016)

- Both companies have appealed to the Competition Appeal Tribunal and the case is pending.

SA: *Sasol Chemical Industries v the Commission*

- **Background:**
  - The South African Competition Tribunal, following a complaint referral from the Commission, held that Sasol had contravened section 8(a) of the Competition Act by charging excessive prices in relation to propylene and polypropylene. The Tribunal had imposed administrative penalties of ZAR534 million upon Sasol, as well as other behavioural remedies.
  - The Competition Appeal Court, by unanimous decision, upheld Sasol's appeal of the Tribunal's decision and overturned the Tribunal's decision, including the imposition of administrative penalties. In its decision, the Competition Appeal Court held that the Tribunal had failed in "the proper application of s 8(a)".
  - In its appeal to the Constitutional Court, the South African Commission requested that the Appeal Court's decision be overturned and that the administrative penalties be increased for both propylene and polypropylene.
  - The Constitutional Court, however, dismissed the Commission's application on the basis that "*it bears no success*".

SA: *Sasol Chemical Industries v the Commission*

- **Key learnings and findings:**
  - Proper interpretation of the phrase “economic value”;
  - Manner in which the reasonableness of the relation being price and economic value is to be assessed.
  - The Appeal Court found that “[a] *measure of deference is called for in these enquiries, not only because of the importance of freedom of pricing, but also to obviate converting courts into price* [regulators]”.

Excessive pricing: conclusion

- The jury is still out
- Key questions to be determined:
  - To what extent does legislation impact independent pricing decisions?
  - To what extent do different rules apply to innovation markets?
- Important considerations:
  - Developing a coherent jurisprudence to inform commercial decision-making and create transparency for the general public.
- What latitude will the Competition Authorities and Courts give to "innovative" products, such as pharmaceuticals?

IMPACT OF LEGISLATIVE FACTORS ON THE PHARMACEUTICAL ARENA

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The impact of legislative factors on pricing

- To what extent do legislative factors impact on pricing and undermine arguments about firms allegedly using their market power to price anti-competitively?

Impact of Single Exit Pricing on excessive pricing

- Does single exit pricing regulation preclude pharmaceutical companies from engaging in excessive pricing?
- The South African pharmaceutical industry underwent fundamental change in 2003. An amendment to the Medicines and Related Substances Act prescribed a Single Exit Price regime, which stipulates that a medicine may only be sold at a single **approved** price throughout the supply chain.
- In terms of section 18A of the Medicines and Related Substances Act, no person shall supply any medicine according to a bonus system, rebate system or any other incentive scheme.
  - Schedule 0 products are currently exempted from the provision of sections 18A and 22G.

Single exit pricing: Considerations

- Is single exit pricing a defence to claims by the Commission of excessive pricing?
- Are the use of the following evidence of countervailing power by medical schemes:
  - Formularies;
  - prior approvals for Biologics and Immuno Therapy treatment;
  - sub-limits for certain drugs; and
  - Maximum Medical Aid Pricing.
- What role, if any, does mandatory generic substitution (section 22F of the Medicines Act) play in excessive pricing cases?

Conclusion

- The concept of economic value is a matter of judgment, which involves a considerable margin of appreciation, based on an objective assessment of the particular case;
- As a matter of law, parties' subjective beliefs as to what is a fair or reasonable price are not relevant for the assessment;
- The economic value of a product may exceed its cost plus as a result of some non-cost related factors, including additional benefits not reflected in the costs of supply or any particular enhanced value from the customer's perspective.
- Economic value is not simply whatever price a product or service would fetch, or which "*the market will reasonable bear*".

THANK YOU

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