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Discussion on "Competition in Healthcare Markets: Access and Affordability"

Competition Commission of South Africa

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Discussion on "Competition in healthcare markets: access and affordability"[1]

Friday, 12 July 2019

Room

Cost and access to healthcare remains a pervasive subject across the globe. The health of citizens is inextricably linked to a country's productivity and economic development. This is recognised in the third United Nations Sustainable Development Goals (SDG 3 also UN SDGs).

The global market share stability of certain pharmaceutical firms raises concerns about the extent and nature of competition within pharmaceutical markets. This is an important consideration in markets where governments remain large customers and shoulder the cost of healthcare.

The use or misuse of intellectual property also plays a crucial role in determining the affordability of medicines which remain under intellectual property protection. Arrangements between pharmaceutical firms which prevent market entry of cheaper alternatives or those which enable firms to charge excessive or unfair prices raise competition concerns.

Given these concerns, several competition authorities across the world are undertaking competition investigations in order to ensure that these markets remain competitive and engender access to affordable healthcare for all.

This session will consider and discuss the drivers of access to affordable healthcare and the role of competition regulation in ensuring that healthcare markets work to attain this goal. In doing so, the session will also consider the latest competition law cases underway which seek to address access and affordability across healthcare markets.

[1] Prepared by the Competition Commission of South Africa on behalf of the United Nations Conference on Trade and Development Secretariat, Competition Law and Policy, July 2019

A. Introduction

1. The World Health Organisation (**WHO**) recognises that *"Good health is essential to sustained economic and social development and poverty reduction…At the same time, people need to be protected from being pushed into poverty because of the cost of health care."*[2]

2. Access to affordable healthcare is part of the universal discourse, not just in relation to competition law and access primarily to affordable medicines, but as part of the broad policy discussion of how healthcare markets should work and the extent that governments ought to intervene to ensure that these markets function to enable all citizens access to affordable healthcare. There remains and persists calls and debates, in for example, the United States of America for *"Medicare for All"* and the recent lawsuit filed against generic drug makers for alleged price-fixing.[3]

3. WHO literature further notes that access to affordable healthcare should encompass essential dimensions, including:[4]
   3.1. **Physical accessibility** – this encompasses the availability of good health services within reason for those who need them i.e. reasonable opening hours, appointment systems, reasonable service delivery that allow people to obtain the services when they need them.
   3.2. **Financial affordability** – this encompasses the ability for people to pay for healthcare services without falling into financial hardship, taking into account not only the price of the health services but also indirect and opportunity costs such as costs of transportation to and from healthcare facilities and of taking time away from work.

4. It is trite to state that healthcare markets operate differently from most commodity-based markets and are subject to socio-economic and political factors. In some instances, healthcare and access to healthcare are considered a human right, enshrined in some countries' constitutions[5] and afforded to every citizen. This invariably places social and financial obligations on governments to ensure that citizens are provided with access to affordable and quality healthcare.

5. Many countries, especially in developing economies or economies in transition, face the challenge of limited financial resources in order to ensure the provision of healthcare to all. The Organisation

[2] https://www.who.int/healthsystems/universal_health_coverage/en/ - Universal health coverage: launch of pilot programmes in Kenya
[3] https://www.nytimes.com/2019/05/11/health/teva-price-fixing-lawuit.html - *"Teva and Other Generic Drugmakers Inflated Prices Up to 1,000%, State Prosecutors Say"* by Heather Murphy and last accessed on 17 May 2019
[4] https://www.who.int/bulletin/volumes/91/8/13-125450/en/
[5] For example, The Constitution of the Republic of South Africa (1996) section 27(1)(a) states that, *"Everyone has the right to have access to health care services, including reproductive health care."*

for Economic Development and Cooperation (**OECD**) noted that in most countries health services are obtained either through government funding or some form of compulsory health insurance system. For example, in the United Kingdom, Iceland, Denmark and Sweden, 80% of health services are financed by the government.

6. Conversely, out-of-pocket payments represent a fifth of all spending on health services in OECD countries. The OECD notes that out-of-pocket payments affect poorer households more adversely than richer households. This aspect is essential applying the WHO dimensions, in particular, physical access and financial affordability in providing access to healthcare. OECD data reflects that for example, in Latvia and Mexico households finance 40% of healthcare directly compared to 10% in France where government spending on health services is greater.[6]

7. According to the WHO, in 2016, the world spent US$7.5 trillion on health, representing close to 10% of global gross domestic product (**GDP**). The average per capita health expenditure was US$1,000, but half of the world's countries spent less than US$50 per person.[7] However, in 2010, an estimated 808 million people (11.7% of the world's population) spent at least 10% of their household budget on out-of-pocket payments for health services. For 179 million of these people, such payments exceeded a quarter of their household budget. An estimated 97 million people (1.4% of the world's population) were impoverished by out-of-pocket health-care spending in 2010.[8]

8. The inextricable link between health and development means that the subject of healthcare cannot be ignored. WHO continues, year in and year out, to record that preventable diseases, such as malaria continue to kill as many as 435 000 people annually primarily due to a lack of funds as well as people's ability to access such life-saving medicines. The role of intellectual property in price determination of pharmaceuticals may mean that, *"…extremely high prices charged for newly approved drugs for the treatment of cancer and hepatitis C are indicative of a trend in which new medicines are nearly always more expensive…In addition, prices for older off-patent products can increase astronomically when a new company gains a monopoly on the market. Recent controversies in the United States – the overnight 5000% increase in the price of pyrimethamine and the price increase for epinephrine auto-injection devices – are the most egregious manifestations of this second trend."*[9] WHO also records that communicable, nutritional, maternal

[6] www.oecd.org/health, "Focus on Spending on Health: Latest Trends" June 2018

[7] https://apps.who.int/iris/bitstream/handle/10665/276728/WHO-HIS-HGF-HF-WorkingPaper-18.3-eng.pdf?ua=1

[8] WHO World Health Statistics 2018: Monitoring Health for the SDGs

[9] See WHO, "Access to medicines: making market forces serve the poor", available at https://www.who.int/publications/10-year-review/medicines/en/index7.html last accessed on 22 May 2019

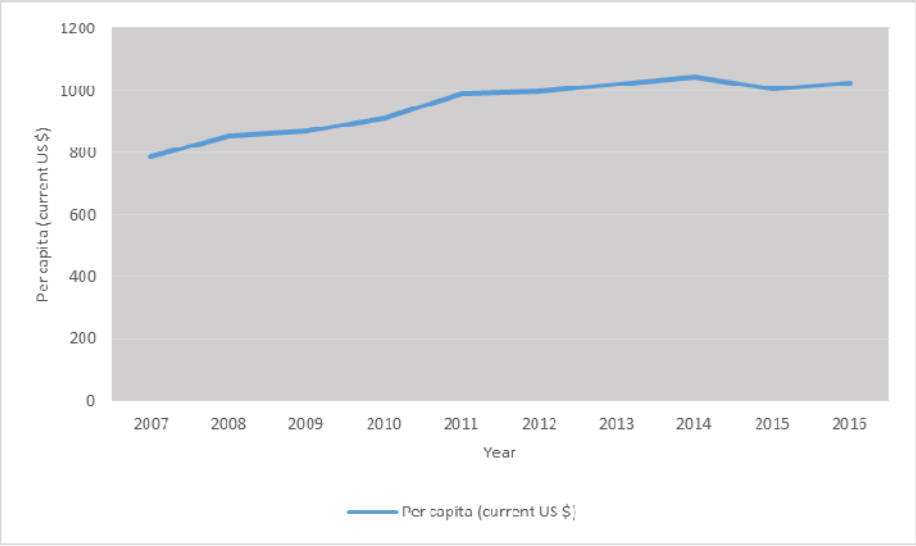
and perinatal remain the highest causes of death in the African Region with HIV/AIDS ranking second in these causes.[10]

9. This brief note will, therefore, look at trends across the globe and explore the role of competition enforcement in continuing to contribute to lowering barriers to access affordable and quality healthcare. It will further explore the policy developments occurring across the globe which seek to facilitate and enable access to affordable and quality healthcare for all, alongside competition enforcement action.

B. Global overview – healthcare

10. The global financial crisis saw a decline on public expenditure by governments in general, impacting on budget allocations for essential goods such as education and healthcare. However, this has taken a taken a turn with per capita health expenditure rising to a level of just above US$1000 as demonstrated in Figure 1 below:

Figure 1: Current global health expenditure per capita (current US$)



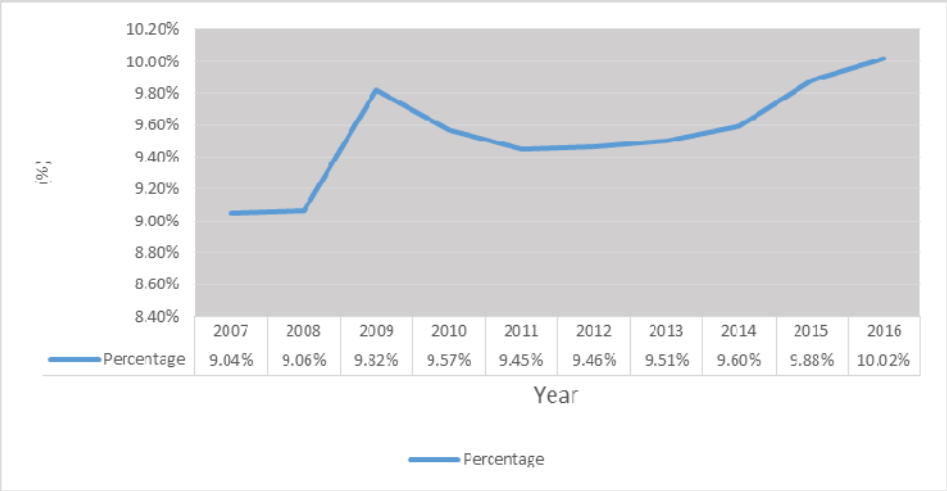
Source: World Bank[11]

11. The reasons for this increase vary from increased demand for healthcare services to increased and (recovered) healthcare spending following the economic crisis of 2008. As health expenditure typically follows economic growth it is also notable that global healthcare expenditure as a

[10] https://www.who.int/gho/mortality_burden_disease/causes_death/top_10/en/
[11] https://data.worldbank.org/indicator/SH.XPD.CHEX.PC.CD?end=2016&start=2007

percentage GDP has increased over the period 2007 to 2016 from 9.04% in 2007 to 10.2% in 2016 (see figure 2 below).

Figure 2: Current global health expenditure as a percentage of GDP



Source: World Bank[12]

12. The OECD reported wide variations across member countries in terms of the GDP percentage spend on health. It is notable that several factors may affect this percentage including the countries' domestic policies, socio-political position, state of development and government spending in relation to private insurance, out-of-pocket payments and other international aid. According to WHO, public spending on health increased as country income grew with the higher income countries having increased their allocation and lower income countries lagging.[13]

13. Medicines and pharmaceuticals also play a significant role in the cost and quality of healthcare across the globe and many countries have introduced initiatives to reduce the cost of pharmaceuticals as a component of healthcare. The provision of appropriate medicines of assured quality, in adequate quantities and at reasonable prices remains a concern for global and national policymakers and agencies implementing health activities and programmes.

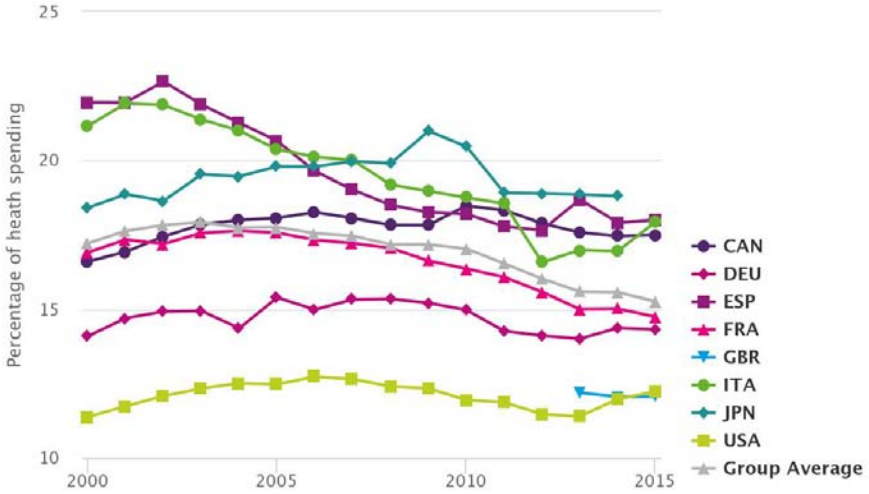
14. In 2011 WHO reported that the consumption of medicines was on the increase with medicines for chronic conditions taking up a significant portion of the volumes for out-of-hospital care.[14] It appears evident that factors such as increases in life expectancy, changes in fertility and the

[12] https://data.worldbank.org/indicator/SH.XPD.CHEX.GD.ZS?end=2016&start=2007&view=chart
[13] https://www.who.int/health_financing/documents/health-expenditure-report-2018/en/ "Public Spending on Health: A Closer Look at Global Trends". 2018
[14] https://www.who.int/medicines/areas/policy/world_medicines_situation/en/ "The World Medicines Situation Report". 2011

increase in the burden of disease would result in the increase of demand for pharmaceutical products and other resultant factors such as availability, pricing and affordability.

15. The OECD has reported that pharmaceutical expenditure is on the decline for many of its member countries post-2008. It is notable that here the OECD defines pharmaceutical spending as expenditure on prescription medicines and self-medication, often referred to as over-the-counter products. In some countries, other medical non-durable goods are also included. Pharmaceuticals consumed in hospitals and other healthcare settings are excluded. Figure 3 below illustrates the pharmaceutical spending as a percentage of health spending for the period 2000 to 2015:

Figure 3: Pharmaceutical spending as a percentage of health spending 2000 – 2015 (OECD)



Source: OECD Pharmaceutical spending (indicator)[15]

16. The decreasing costs of pharmaceuticals are often attributed to the introduction and use of more generics in these markets.

17. Over and above the factors noted above, competition concerns persist and are at times attributed to the cause of rising prices in the healthcare markets. The United Nations Conference on Trade and Development (UNCTAD) noted that between 2010 and 2013 the following firms accounted for the top 10 pharmaceutical firms in the world by revenue.[16]

[15] https://data.oecd.org/healthres/pharmaceutical-spending.htm

[16] Seventh United Nations Conference to Review All Aspects of the Set of Multilaterally Agreed Equitable Principles and Rules for the Control of Restrictive Business Practices
Geneva, 6–10 July 2015, *"The role of competition in the pharmaceutical sector and its benefits for consumers."* Note by the UNCTAD secretariat

Table 1: Top 10 Pharmaceutical firms by Revenue (2010 – 2013)

Top 10 pharmaceutical firms by revenue	2013	2012	2011	2010
1	Pfizer (United States of America)	Pfizer	Pfizer	Pfizer
2	Novartis (Switzerland)	Novartis	Novartis	Novartis
3	Roche (Switzerland)	Merck and Co.	Merck and Co.	Sanofi
4	Merck and Co. (United States)	Sanofi	Sanofi	Merck and Co.
5	Sanofi (France)	Roche	Roche	GlaxoSmithKline
6	GlaxoSmithKline (United Kingdom of Great Britain and Northern Ireland)	GlaxoSmithKline	GlaxoSmithKline	Roche
7	Johnson and Johnson (United States)	AstraZeneca	AstraZeneca	AstraZeneca
8	AstraZeneca (United Kingdom)	Johnson and Johnson	Johnson and Johnson	Johnson and Johnson
9	Lilly (United States)	Lilly	Lilly	Lilly
10	AbbVie (United States)	Teva	Teva	AbbVie

18. The information in Table 1 above illustrates that over the 4-year period, the positions of the firms remained largely unchanged. Compared to Table 2 below, apart for the emergence of Hoffmann-La Roche and Gilead Sciences Inc., the period between 2014 and 2016 also saw more or less the same firms in the top ten spots for global pharmaceutical firms. This stickiness in market positions over time does raise some concerns with buyers of medicines especially when it is coupled with a concomitant rise in the cost of healthcare services generally.

Table 2: Top 10 Pharmaceutical firms by Revenue (2014 – 2016)

Top 10 pharmaceutical firms by revenue	2016	2015	2014
1	Pfizer	Pfizer	Novartis
2	Novartis (Switzerland)	Novartis	Pfizer
3	F. Hoffmann-La Roche Ltd	F. Hoffmann-La Roche Ltd	F. Hoffmann-La Roche Ltd
4	Sanofi (France)	Merck and Co.	Sanofi
5	Merck and Co. (United States)	Sanofi	Merck and Co.
6	Johnson and Johnson (United States)	Gilead Sciences Inc	Johnson and Johnson
7	GlaxoSmithKline (United Kingdom of Great Britain and Northern Ireland)	Johnson and Johnson	GlaxoSmithKline
8	Gilead Sciences Inc.	GlaxoSmithKline	AstraZeneca
9	AbbVie (United States)	AstraZeneca	Gilead Sciences Inc.
10	Amgen Inc.	AbbVie	AbbVie

Source: PM Group, Top 25 pharma companies by global sales. PM Live, available at http://www.pmlive.com/top_pharma_list/global_revenues, accessed 13 May 2019

C. Competition law enforcement action

19. Competition policy has over time, been a key intervening tool in addressing market inefficiencies and rising prices in healthcare markets. UNCTAD notes that *"Competition is important because it compels industry to provide higher quality goods and services at lower prices. In the pharmaceutical industry, competition can motivate brand companies to create new and improved medicines and encourage generic companies to offer less expensive alternatives."*[17]

20. Undoubtedly, the pricing of pharmaceuticals and pricing across the healthcare system is complex and varies from country-to-country. Where there is large public spending in the healthcare system, Government is generally a large customer of pharmaceuticals, medical devices and healthcare services. Moreover, sectoral regulation, as well as price regulation, may be applicable especially in relation to pharmaceuticals. This interplay means that competition intervention, especially in relating to pricing, becomes more complex, raising the probability of over and under enforcement in decision-making processes of competition regulators and sector regulators.

21. The complexity is further compounded by the fact that in pharmaceutical markets, intellectual property rights play a significant role in promoting innovation and research and development (**R&D**). Therefore, from a policy perspective, this requires that a balance is struck between incentivising innovation and allowing innovation to permeate throughout society for the benefit of all.

22. From a competition law perspective, the scope of intellectual property rights (**IPRs**) is concerned with the balance between granting firms the appropriability of their innovations and the desire that the benefit of such innovations spread to other firms and to consumers. Granting innovators with an exclusive legal right to the economic exploitation of the innovation for a period, 20 years at a minimum, forms part of the ecosystem that creates this balance. Theoretically, IPRs can promote the creation of innovations and economic advancement and consumer welfare. The earning of profits through the exploitation of IPRs either by the innovator or by others through licensing is both the reward for innovative effort and a tangible incentive for others to undertake R&D efforts towards further innovation. This may also engender competition amongst firms to produce innovative products for the benefit of consumers.

23. However, competition law enforcement should not be laissez-faire towards firms' exercise of IPRs given their potential to restrict competition through predominantly the abuse of dominance such as excessive pricing or the refusal to grant access to an essential facility. This may lead to a

[17] Ibid

reduction in consumer welfare through the lack of competitive pricing or the lack of product choices.

24. Recently there have been increased enforcement action across the globe against pharmaceutical firms. Most competition enforcement action in the healthcare market is largely related to pharmaceuticals rather than healthcare facilities and practitioners. The latter is usually dealt with through merger enforcement through the regulation of hospital mergers (see Box 1) and to some extent cartel enforcement and exemption applications.

Box 1 – Brazil Merger Case No. 08700.003978/2012-90 (Merger Regulation)

Unimed Franca tried to buy 5,555,662 voting shares of the Regional Hospital of Franca. Unimed Franca is a cooperative medical services, which in addition to offering individual, family and cooperative health plan, also has its own and accredited laboratories, its own clinics and accredited network, with various activities, health promotion center, physiotherapy center, oncology service, specialty center for multi-professional care (nutritionist, psychologist), prehospital care service and its own Hospital (São Joaquim Hospital and Maternity Hospital).

Regional Hospital de Franca S.A. is a Brazilian joint stock company offering individual, family and cooperative health insurance (Regional Hospital Health Plan), with a clinical staff of 120 physicians and a hospital. In this specific case, it was pointed out that this market could be segmented at least in two dimensions:

a) Hospital Medical Service:
   - Medical Center (that could represent a bundle of certain services, such as: Ambulatory / Emergency, Examinations of Laboratory Medicine, Diagnostics by Image, Diagnostics by Graphical Methods);
   - Hospitals (that could provide also a bundle of certain services, for example: General Hospital, treatment of serious cases, Specialized treatment, Ambulatory / Emergency Medicine, Laboratory Tests, Image, Diagnostics by Graphical Methods);

b) Diagnostic Medicine Support Service:
   - Examinations of Laboratory Medicine (Clinical Analysis);
   - Laboratory Tests (Pathological Anatomy and Cytopathology);
   - Exams to Support Other Laboratories (Clinical Analysis);
   - Examinations to Support Other Laboratories (Pathological Anatomy and Cytopathology);
   - Diagnostic Exams by Graphic Methods (holter, map, electrocardiogram, electroencephalogram, etc.);
   - Diagnostic Tests, by Image (Magnetic Resonance, ultrasound, densitometry, mammography, x-ray, etc.)

In this specific case, CADE defined the relevant market for hospital medical services (*general hospital*), within the radius of 10 km of the hospitals in question. In order to analyze the concentration, CADE used the Herfindahl-Hirschman index (**HHI**). Before the merger, the HHI of the market was 3855,3. After the merger the HHI was 7317,6. Thus, there was a very strong concentration in the market. CADE rejected the acquisition, by Unimed Franca, of the control of the Regional Hospital of Franca, in São Paulo, and of its health plan. CADE's former President, Vinicius Marques de Carvalho, presented a view in which he highlighted that the operation resulted in concentration that exceed 80% of the market for medical and hospital services and individual and collective health plans in Franca and the municipalities in the region. Competitive concerns also included high barriers to entry and low rivalry.

25. The European Commission recognises that high prices of medicines impose a high burden on national healthcare systems, where pharmaceuticals already account for a significant share of spending. It is estimated that the total NHS spending on medicines in England grew from £13 billion in 2010/11 to £17.4 billion in 2016/17. This is an average growth of around 5% a year, signaling a rate of increase that is substantially faster than for the total NHS budget over the same period.[18] This, therefore, makes effective competition from generics a vital source of price competition on pharmaceutical markets in order to significantly drive down prices.[19] The concerns

[18] https://www.kingsfund.org.uk/sites/default/files/2018-04/Rising-cost-of-medicines.pdf

[19] European Commission, Report from the Commission to the Council and the European Parliament, *"**Competition Enforcement in the Pharmaceutical Sector:** European competition authorities working together for affordable and innovative medicines"*

about pharmaceutical pricing have seen a recent surge in competition authorities undertaking investigations into access to affordable medicines largely through excessive pricing investigations and to some extent pay-for-delay arrangements.

Pricing investigations

26. In the recent past, the European Commission and various national competition authorities (NCA) within the European Union have undertaken pricing related investigations in the pharmaceutical market, including:
    26.1. September 2016 – the Italian NCA imposed a EUR 5.2 million fine on the pharmaceutical company Aspen for abusing its dominant position by setting unfair prices for important off-patent cancer medicines in Italy namely, Leukeran, Alkeran, Purinethol and Tioguanine.
    26.2. December 2016 – the United Kingdom NCA found that Pfizer and Flynn had each abused their respective dominant position by imposing unfair prices for phenytoin sodium capsules (an epilepsy medicine) manufactured by Pfizer in the United Kingdom.
    26.3. May 2017 – EU-wide investigation into Aspen Pharma relating to unfair pricing concerning cancer medicines.

27. Many other jurisdictions across the globe are also undertaking similar pricing investigations as set out in Box 2.

28. A recent paper by the OECD[20] considered whether it is appropriate for competition regulators to intervene in pharmaceutical healthcare markets against excessive pricing. In doing so it considered arguments for and against intervention including:
    28.1. A dominant firm earning excessive profits in a market will signal to attract new entrants into the market which will erode the excessive profits as new entrants compete against the dominant firm
    28.2. The monitoring of *ex ante* compliance with excessive pricing rules create problems including identifying the appropriate benchmarks such as identifying the "competitive price" and the cost of production of a dominant firm
    28.3. Over-intervention by competition regulators in excessive pricing matters risk long-term anti-competitive effects such as reducing the incentives for dominant firms to invest and attracting new entry in the market

[20] https://one.oecd.org/document/DAF/COMP(2018)12/en/pdf

28.4. Excessive pricing investigations place competition regulators and courts closer to that of pricing regulator which may not be appropriate

28.5. Competition policy exists to limit the potential for exploitative behaviour and to lower prices for the benefit of consumers.

28.6. There could be markets where high prices would not lead to self-correction within a reasonable period

28.7. Exploitative abuse taking place over a prolonged period usually occur where there are high and non-transitory barriers to entry or expansion, preventing competitors from undercutting the dominant firm and eroding its market position

While price regulation should usually be left to specialised sectoral regulators, competition authorities may have a role to play as residual regulators or regulators of last resort

29. The OECD concludes that where the conditions justify bringing enforcement action against excessive pricing competition authorities ought to pursue such cases. However, other tools are available to competition authorities outside of outright enforcement action such as market studies and joint efforts with sector regulators through advocacy. Effective intervention will mean that competition authorities need to have a deep understanding of these markets.

Box 2 – Selected Pricing-Related Enforcement Action by Competition Authorities Across the Globe

India

This is an investigation against Roche and its two group firms for alleged anti-competitive conduct with respect to its biological cancer drug, Trastuzumab. The allegation comprised of pricing as well as non-pricing abuses. Though the Commission found a *prima-facie* case of contravention of the provisions of the Act, the investigation direction was only with regard to denial of market access because of the abusive strategies adopted by Roche *e.g.* denigrating the image of the biosimilars. With regard to the allegation of excessive pricing, as stated earlier, the Commission was of the opinion that being the innovator, Roche might have invested huge sums on research and development of Trastuzumab and initial high prices can be attributable to the reward for such innovation. This case is presently under investigation.

Denmark

Syntocinon is an out-of-patent drug containing oxytocin, an active substance given to pregnant women in connection with childbirth in Danish hospitals. CD Pharma had an exclusive distribution agreement with the producer of Syntocinon, which ensured its ability to supply the market. During 2007-2014, the price of drug Syntocinon was stable around DKK 44 (EUR 5.9).

The wholesale buyer for hospitals, Amgros, put out a tender on Syntocinon which was won by a parallel importer. However, this company was unable to provide Amgros with the full amount of required Syntocinon. Since CD Pharma was the only alternative supplier in the Danish market, Amgros had to buy a residual quantity of Syntocinon from CD Pharma, which on this occasion increased the price of the drug by 2,000%. The Danish Competition Authority ruled that CD Pharma's price increase amounted to an abuse of a dominant position and ordered it to refrain from similar behaviour in the future.

South Africa

The CCSA initiated complaints of excessive pricing against two pharmaceutical manufacturers, Roche Holding AG and Genentech Inc. alleging that Roche and its wholly-owned subsidiary Genentech contravened the Competition Act by engaging in excessive pricing, exclusionary conduct and price discrimination with regard to the sale and supply of a drug named Trastuzumab, sold under Roche's brand names, Herceptin and Herclon for the treatment of breast cancer.

The information obtained by the CCSA prior to the initiation of the complaint indicated that:

- Trastuzumab is sold at excessive prices in South Africa by Roche and Genentech. For example, a 12-month course of Herceptin in the private sector costs over R500 000 ($35 000) or more if a high dosage is required and as such most patients are unable to afford the treatment
- Roche and Genentech use strategies such as 'ever greening' and 'patent thickening' to delay and/or prevent entry of generic alternative breast cancer drugs in South Africa
- Roche and Genentech charge their customers different prices for breast cancer medicines. For example, the private sector is charged approximately double the price paid by the public sector for aforementioned drugs.

United Kingdom

The CMA imposed fines of nearly £90 million on Pfizer and Flynn Pharma for charging excessive and unfair prices for phenytoin sodium capsules, a drug used for the treatment of epilepsy; Pfizer was the manufacturer of the drug and Flynn the distributor. Until September 2012 Pfizer manufactured and distributed the drug under the brand name 'Epanutin': as long as it was branded it was subject to price regulation. Pfizer sold the UK marketing authorisations for the drug to Flynn which de-branded, or 'genericised', the drug, at which point price regulation ceased to apply. Both Pfizer as manufacturer and Flynn as distributor raised the price of the drug by a considerable amount, so much so that the CMA concluded that they were each guilty of excessive and unfair pricing. The CMA found that the prices were abusively high, because they materially exceeded cost plus a reasonable rate of return, they were several multiples of the prices that Pfizer had charged for Epanutin and they had a materially harmful effect on the health service[83]. A four-week appeal against the decision ended on 24 November 2017, and the CAT's judgment is awaited.

Italy

In September 2016, the Italian NCA imposed a EUR 5.2 million fine on the pharmaceutical company Aspen for abusing its dominant position by setting unfair prices for important medicines in Italy. These off-patent medicines included Leukeran, Alkeran, Purinethol and Tioguanine, which were used to treat cancer. They had been included in a wider package of pharmaceutical products, for which Aspen purchased the marketing rights from the originator GlaxoSmithKline in 2009. The NCA found that Aspen abused its dominant position in Italy by imposing price increases of between 300 % and 1,500 % and by applying particularly aggressive tactics towards the Italian Medicines Agency in negotiating these prices. Aspen even threatened to *'initiate supply termination'*, i.e. withdraw the drugs if the Agency did not accept the requested higher prices. Following the acceptance of price increases, Aspen's consultant concluded: '*I wouldn't [have] expected to conclude the negotiation so favourably, but I remember when you told me in Rome that everywhere at the beginning it seems it was kind of 'mission impossible' and then the prices increase where always authorised …Let's celebrate!*'.

The NCA also ordered Aspen to put in place measures aimed at, among other things, setting new fair prices for the medicines concerned. Following the NCA's order and after protracted negotiations, Aspen reached an agreement on pricing with the Italian Medicines Agency. On 13 June 2018 the NCA determined that Aspen was compliant with its order and estimated that the concluded agreement would save the Italian National Health Service EUR 8 million annually.

The NCA decision was upheld by the Administrative Regional Court63. An appeal against this judgment is pending before the Italian State Council.

The investigation of this complaint is still ongoing

Pay for delay

30. The Report from the Commission to the Council and the European Parliament on Competition Enforcement in the Pharmaceutical Sector (2009-2017) defines pay-for-delay agreements as, *"…encompass[ing] a variety of arrangements between originator and generic companies, whereby the generic company agrees to restrict or delay its independent entry onto the market in exchange for benefits transferred from the originator. In other words, the originator company pays its competitor, the generic company, to stay out of the market for a shorter or longer period of time."*[21]

31. The competition harm arising out of pay-for-delay arrangements is that the originator and the generic potential entrant benefit from these arrangements through increased profits. However, patients and government lose out on savings that would have arisen by the entry of the generic in order to erode the pricing margins of what now will be off-patent medicines. Rather, patients and governments will continue to pay prices afforded to the originator in the period of exclusivity which will be extended by the pay-for-delay arrangement.

32. Based on recent developments by competition authorities relating to the pricing of medicines, there is some benefit to competition law enforcement brought about by the exploitation of IPRs and to some extent regulatory failure in keeping prices down.

[21] Report from the Commission to the Council and the European Parliament on Competition Enforcement in the Pharmaceutical Sector (2009-2017), *"European competition authorities working together for affordable and innovative medicines"*

Box 3 – Examples of Pay-For-Delay

United Kingdom

Johnson & Johnson developed fentanyl, a potent painkiller used especially for cancer patients, and have commercialised it in different formats including a patch. In 2005, Johnson & Johnson's patents on the fentanyl patch expired in the Netherlands and Novartis' subsidiary Sandoz was on the verge of launching its generic fentanyl patch.

However, in July 2005, instead of launching its generic product, Sandoz concluded a 'co-promotion agreement' with a subsidiary of Johnson & Johnson. The agreement provided that Sandoz would not be allowed to enter the Dutch market in return for monthly payments calculated to exceed the profits that Sandoz expected to obtain from selling its generic product. The agreement was terminated in December 2006 when another generic entered the market.

Contemporaneous internal documents found by the Commission showed that Sandoz decided to abstain from entering the market in exchange for '*a part of [the] cake*', that is for a part of the originator's exclusivity profits shielded from generic competition. Instead of competing, the two rivals agreed to cooperate aiming '*not to have a depot generic on the market and in that way to keep the high current price*'.

The agreement delayed the entry of a cheaper generic medicine for seventeen months and kept prices for fentanyl in the Netherlands artificially high – to the detriment of patients and the Dutch healthcare system. The Commission concluded that the object of this agreement was to restrict competition contrary to Article 101 TFEU and imposed fines of EUR 10.8 million on Johnson & Johnson and EUR 5.5 million on Novartis. The parties did not appeal the Commission's decision.

United States of America

The Federal Trade Commission has reached a global settlement resolving pending claims in three separate federal court antitrust lawsuits involving subsidiaries of pharmaceutical manufacturer Teva Pharmaceuticals Industries Ltd. If approved by the various courts, the stipulated order will prohibit Teva from engaging in reverse-payment patent settlement agreements that impede consumer access to lower-priced generic drugs.

Under the stipulated order for a permanent injunction, Teva is prohibited from entering into a patent infringement settlement agreement that includes a reverse payment transferring value from the brand to the generic. Although Teva is currently bound by a prior order in FTC v. Cephalon, the new order is broader, prohibiting Teva from entering into the two most pernicious and common forms of reverse payments: (1) a side deal, in which the generic company receives compensation in the form of a business transaction entered at the same time as the patent litigation settlement; and (2) a no-AG commitment, in which a brand company agrees not to compete with an authorized generic version of a drug for a period of time. The prior order had not prohibited no-AG commitments. The new revised order, which would last for 10 years from the date of entry, provides immediate relief to consumers, without the costs and risks of trial and appeal in three pending cases.

D. Healthcare – facilities and funding

33. Access to affordable pharmaceutical products forms one facet of access to affordable healthcare. Other inefficiencies can occur within the value chain of the provision of healthcare which have to potential to inhibit universal access and affordability. Such inefficiencies may be caused by, *inter alia*, information asymmetries, including the insured being unable to undertake a qualitative assessment of healthcare received based on the price they pay private insurers/funders, patients being unable to shop around for services and compare prices and service quality and bargaining power between hospitals and medical insurance/funders. These market failures can occur especially where there are regulatory gaps between the public and private healthcare sectors. In most countries private health insurance plugs the gap where public provision is lacking therefore supplementing provision in the public health sector through private-public partnerships in the provision of services.

34. However, there generally is no pricing regulation in the provision of healthcare insurance in most jurisdiction. However, facility-providers such as hospital groups usually negotiate directly with funders/insurers about the cost of the provision of healthcare in their facilities. From a competition perspective in order to mitigate for the bargaining power of either hospital groups or

insurers, some competition authorities have granted exemptions/exceptions to the application of competition law provision in collective bargaining including price-setting in order to ensure affordability and access to the insured.

35. In several jurisdictions, there is general concern about the rise in mergers and acquisitions, particularly in hospital markets, which have led to an increase in levels of concentration. Merger regulation therefore becomes a significant tool available to competition authorities in considering access to healthcare services and reducing associated costs.

36. Healthcare markets are prone to market failure due to extensive information asymmetry which makes it difficult for consumers to assess prices, quality and the necessity of various forms of care, amongst other factors. The intermediation of healthcare decisions by for-profit healthcare providers who can exercise market power and by healthcare insurers, who reduce consumers' and providers' responsiveness to price signals, may place upward pressure on healthcare expenditure in the system overall.

E. Policy developments

37. Given the significant debates surrounding healthcare and pharmaceuticals, it sometimes leads to domestic policy changes. These either entail the review of pricing methodologies in relation to the public procurement of medical services or legislative changes impacting the same markets.

38. In South Africa, the IP Policy – Phase I, as approved by Cabinet in May 2018, proposes key reforms to the current IP regime. The proposed changes will bring South Africa's IP laws in line with the UN SDGs. The pharmaceutical sector is one of the sectors that will be impacted by the proposed key policy reforms that are aimed at advancing South Africa's socio-economic objectives. These reforms include *inter alia* the introduction of substantive search and examination of patents. This represents a departure from the current depository system in terms of which patent applications are not scrutinized to assess compliance with patentability criteria. Practices such as evergreening will be curtailed in the new regime and substantive examination will also curtail the abuse of the IPR system in South Africa while ensuring that genuine innovation is stimulated.

Box 4 – Examples of WTO cases relating to TRIPs and pharmaceuticals

India – WT/DS50/IB/R

The Appellate Body upheld the Panel's finding that India's filing system based on "administrative practice" for patent applications for pharmaceutical and agricultural chemical products was inconsistent with Art. 70.8. The Appellate Body found that the system did not provide the "means" by which applications for patents for such inventions could be securely filed within the meaning of Art. 70.8(a), because, in theory, a patent application filed under the administrative instructions could be rejected by the court under the contradictory mandatory provisions of the existing Indian laws: the Patents Act of 1970.

The Appellate Body agreed with the Panel that there was no mechanism in place in India for the grant of exclusive marketing rights for the products covered by Art. 70.8(a) and thus Art. 70.9 was violated.

India – WT/DS79/R

The Panel held that India's filing system based on "administrative practice" for patent applications for pharmaceutical and agricultural chemical products was inconsistent with Art. 70.8. The Panel found that the system did not provide the "means" by which applications for patents for such inventions could be securely filed within the meaning of Art. 70.8(a), because, in theory, a patent application filed under the current administrative instructions could be rejected by the court under the contradictory mandatory provisions of the pertinent Indian law – the Patents Act of 1970.
The Panel found that there was no mechanism in place in India for the grant of "exclusive marketing rights" for pharmaceutical and agricultural chemical products and thus Art. 70.9 had been violated.

Canada – WT/DS114/R

Stockpiling provision

Canada conceded that the stockpiling provision violated Art. 28.1, which sets out exclusive rights granted to patent owners. Concerning Canada's defence under Art. 30, the Panel found that the measure was not justified under Art. 30 because there were no limitations on the quantity of production for stockpiling which resulted in a substantial curtailment of extended market exclusivity, and, thus, was not "limited" as required by Art. 30. Accordingly, the Panel concluded that the stockpiling provision was inconsistent with Art. 28.1 as it constituted a "substantial curtailment of the exclusionary rights" granted to patent holders.

Regulatory review provision

(Canada also practically conceded on the inconsistency of the provision with Art. 28.1) The Panel found that Canada's regulatory review provision was justified under Art. 30 by meeting all three cumulative criteria: the exceptional measure (i) must be limited; (ii) must not "unreasonably conflict with normal exploitation of the patent"; and (iii) must not "unreasonably prejudice the legitimate interests of the patent owner", taking account of the legitimate interests of third parties. These three cumulative criteria are necessary for a measure to be justified as an exception under Art. 30.
The Panel found that the European Communities failed to prove that the regulatory review provision discriminated based on the field of technology (i.e. against pharmaceutical products in this case), either *de jure* or *de facto*, under Art. 27.1.

Canada – WT/DS153/R

On 2 December 1998, Canada requested consultations with the EC in respect of the protection of inventions in the area of pharmaceutical and agricultural chemical products under the relevant provisions of EC legislation, particularly Council Regulation (EEC) No. 1768/92 and European Parliament and Council Regulation (EC) No. 1610/96, in relation to EC obligations under the TRIPS Agreement. Canada considered that under the above Regulations, a patent term extension scheme, which is limited to pharmaceutical and agricultural chemical products, has been implemented. Canada alleged that Regulations (EEC) No. 1768/92 and (EC) No. 1610/96 are inconsistent with the EC's obligations not to discriminate on the basis of field of technology, as provided by Article 27.1 of the TRIPS Agreement, because these Regulations only apply to pharmaceutical and agricultural products.

Argentina – WT/DS171/R (1999)

On 6 May 1999, the US requested consultations with Argentina in respect of the alleged absence in Argentina of either patent protection for pharmaceutical products or an effective system for providing exclusive marketing rights in such products, and Argentina's alleged failure to ensure that changes in its laws, regulations and practice during the transition period provided under Article 65.2 of the TRIPS Agreement do not result in a lesser degree of consistency with the provisions of the TRIPS Agreement.

Pakistan – WT/DS36/R

In its request for consultations dated 30 April 1996, the United States claimed that the absence in Pakistan of (i) either patent protection for pharmaceutical and agricultural chemical products or a system to permit the filing of applications for patents on these products and (ii) a system to grant exclusive marketing rights in such products, violates TRIPS Agreement Articles 27, 65 and 70. On 3 July 1996, the United States requested the establishment of a panel. The DSB considered the request at its meeting on 16 July 1996, but did not establish a panel due to Pakistan's objection.

39. Within the World Trade Organisation (**WTO**) and notwithstanding the flexibilities afforded by the Agreement on the Trade-Related Aspects of Intellectual Property Rights (**TRIPS Agreement**), including flexibilities to adopt measures that are necessary to protect public health such as compulsory licencing, most WTO Member States have not taken advantage of flexibilities in the face of the concerns raised about access and affordability of healthcare. In the 2017 Edition of the

WTO Dispute Settlement: One-Page Case Summaries, as of 2015 there are or have only been 6 dispute cases relating to the TRIPS Agreement.[22]

40. In Malawi, there are policy changes relating to the regulation of the health insurance industry. Currently, there is no specific legislation that regulates the conduct of health insurance providers and the complex relationship they have with healthcare providers. The Registrar of Financial Institutions is currently coming up with regulations which seek to regulate the industry. Due to a number of anti-competitive and consumer-related complaints that the Competition and Fair Trading Commission of Malawi (CFTM) has received with regard to the health insurance industry, the CFTM is undertaking advocacy to ensure that the regulations that the Registrar is developing do not only address issues relating to financial prudence but also cover issues relating to competition and consumer protection.

41. The CFTM is also looking at the potential to regulated vertical integration where a health insurance company has shares in clinics, hospitals and pharmacies. The CFTM's concern is that such an arrangement is being used to foreclose the health insurance market as well as to divert customers to hospitals that are affiliated to the health insurance company which is enjoying such integration. Such practices are likely to have an impact on competition and reduce consumer welfare.

42. CADE's Department of Economic Studies issued a Technical Note Nº 41/2015/DEE/CADE, in Administrative Proceeding 08700.001180/2015-56, presenting some criticism about the current system. According to the Brazilian System, there are different levels of price ceiling for different competitors that sell the same generic drug, with the exact same active principle. However, CADE pointed out that this system is unfair and anti-competitive stating that, *"There is no justification for such drugs to have different ceiling prices if they are exactly the same active principle. That is, the exact same substance, even referring to generic medicines, may come to have a price ceiling differentiated from its peers, without there being any (technical) reason for it. The mere existence of a differentiated price ceiling is capable of creating a competitive distortion in the market."* CADE is also trying to get closer to Brazilian Health Regulatory Agency - ANVISA and to National Regulatory Agency for Private Health Insurance and Plans - ANS in order to advocate for a stronger competitive environment in the Brazilian market.

[22] Available at https://www.wto.org/english/res_e/booksp_e/dispu_settl_1995_2017_e.pdf and last accessed on 24 May 2019

F. Conclusion

43. Access to affordable healthcare is a subject that will continue to preoccupy policy-makers, sector regulators as well as competition law regulators. Given that healthcare is an essential service and basic human right, the review of policy and regulatory intervention must continue with the aim of ensuring that access is granted to all and at affordable prices.

44. Policies should be enabling policies aimed at ensuring adequate and increased government expenditure in health services as well as an environment allowing for innovation especially in relation to pharmaceuticals. Policies should also seek to ameliorate information asymmetries which would enable patients, who have limited choice in healthcare markets, to have access to useful information enabling patients better decision-making abilities for the most appropriate healthcare providers and medical schemes, as well as healthcare funders' ability to compare cost and quality when contracting providers.

45. The recent rise of pricing interventions by competition regulators presents an interesting drive which echoes policy-makers' concerns about the rise in the cost of medicines. Although there seems to be tension between the pricing of pharmaceuticals and intellectual property rights, these should be complementary where there is no exploitation that warrants the intervention of competition regulators. Whilst this still persists alongside the rising cost of out-of-pocket payments by patients, leaving them in debt, it is likely that policy-makers and regulators will continue to grapple with access to affordable healthcare for all.

46. Competition regulators have an essential role to play in the ecosystem of ensuring that pricing of healthcare remains low and interventions across the globe indicate that such interventions do lead to lowering the cost of healthcare.