



# INTERGOVERNMENTAL GROUP OF EXPERTS ON **COMPETITION LAW AND POLICY**





**DISCUSSION:  
"COMPETITION IN HEALTHCARE  
MARKETS:  
ACCESS AND AFFORDABILITY"**

**FRIDAY 12 JULY 2019  
ROOM XVII, PALAIS DES NATIONS,  
GENEVA**

**Hardin Ratshisusu**

**Deputy Commissioner**

**Competition Commission of  
South Africa**





# OUTLINE

- INTRODUCTION
- GLOBAL OVERVIEW
- COMPETITION LAW AND POLICY ISSUES
- TRADE-RELATED ISSUES
- CONCLUSION AND RECOMMENDATIONS





## World Health Organisation

### World Health Organisation – essential dimensions to healthcare

- **Physical accessibility** – encompasses the availability of good health services within reason i.e. reasonable opening hours, appointment systems, reasonable service delivery
- ...
- **Financial affordability** – encompasses the ability for people to pay for healthcare services without falling into financial hardship i.e. the price of the health services, indirect and opportunity costs such as costs of transportation to and from healthcare facilities and of taking time away from work

*“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.”*

SOURCE: WHO. Universal health coverage: launch of pilot programmes in Kenya (2018)



# GLOBAL OVERVIEW: ACCESS AND AFFORDABILITY

UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT

UNCTAD

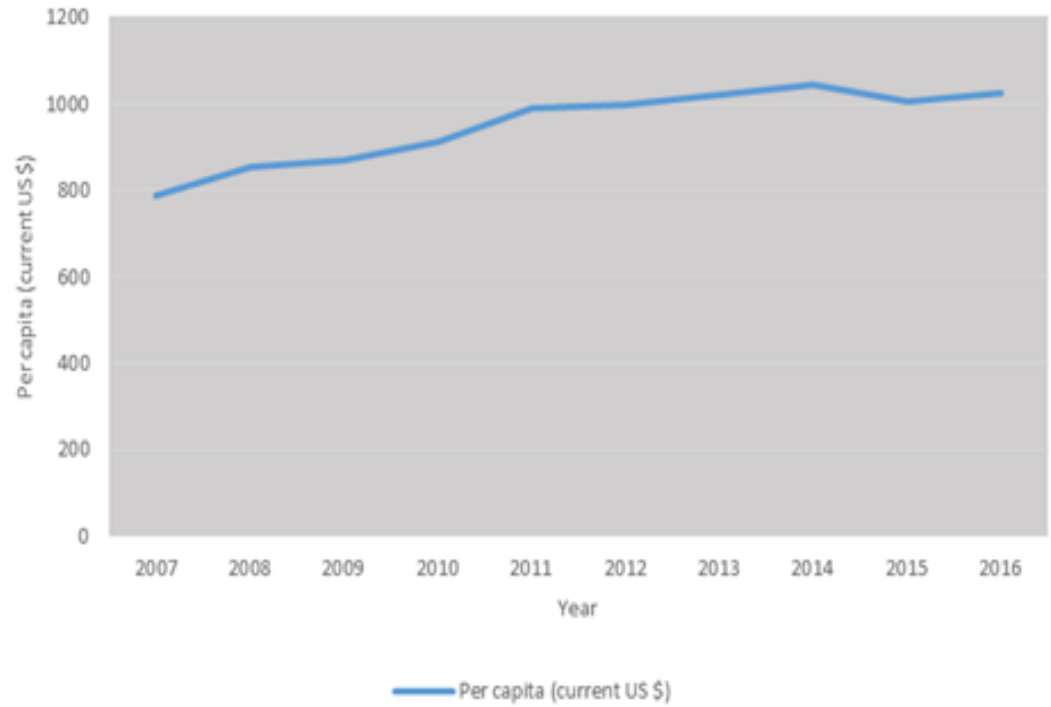


- In 2016 the world spent US\$7.5 trillion on health and average per capita health expenditure was US\$1,000, but half of the world's countries spent less than US\$50 per person (WHO World Health Statistics 2018: Monitoring Health for the SDGs)
- In most countries, health services are obtained either through government funding or some form of compulsory health insurance system
- Out-of-pocket payments affect poorer households more adversely than richer households e.g. Latvia and Mexico households finance 40% of healthcare directly compared to 10% in France where government spending on health services is greater (OECD "Focus on Spending on Health: Latest Trends" June 2018)
- WHO records that preventable diseases, such as malaria continue to kill up to 435 000 people annually due to lack of funds and inability to access life-saving medicines
- In 2010 an estimated 808 million people spent at least 10% of their household budget on out-of-pocket payments for health services. For 179 million of these people these payments exceeded a quarter of their household budget and an estimated 97 million of these people were impoverished as a result (WHO 2018)
- 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

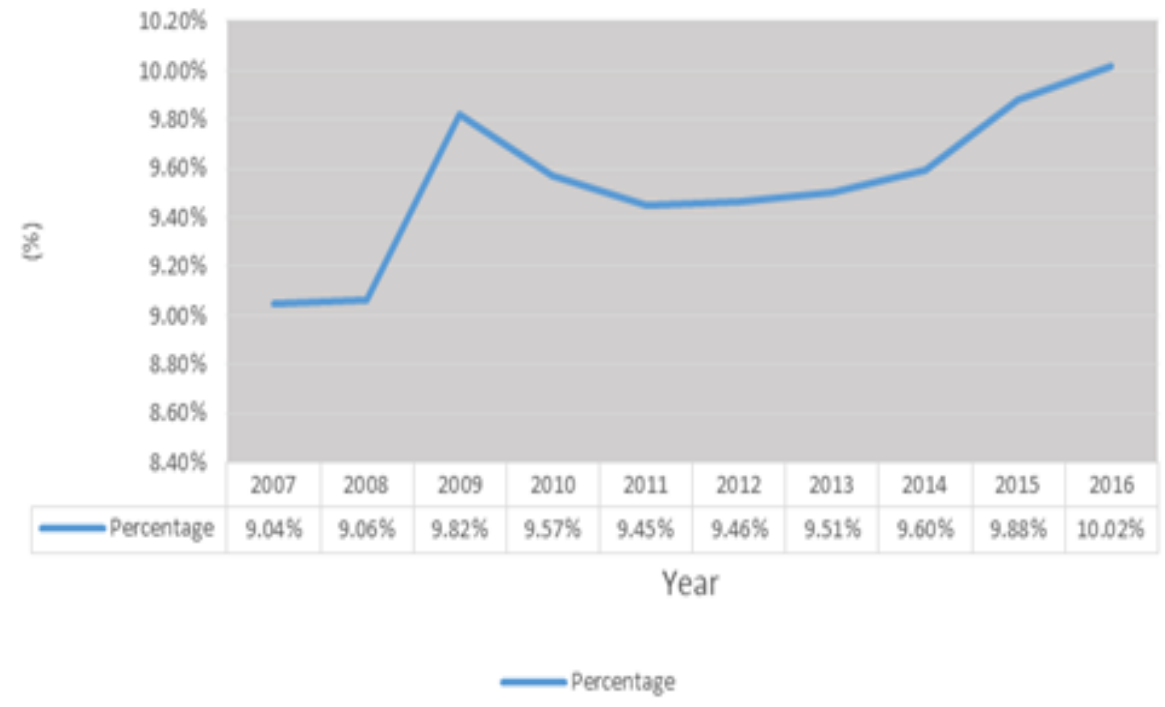




## Current global health expenditure per capita (current US\$)

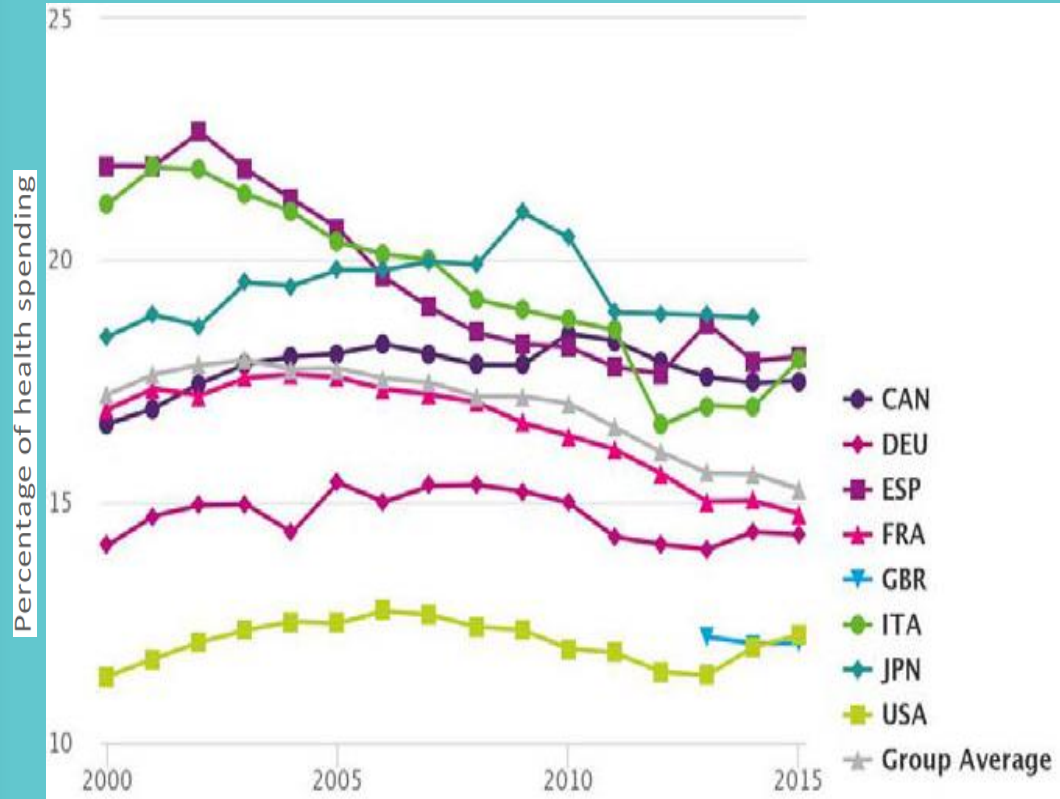


## Current global health expenditure as a percentage of GDP



# GLOBAL OVERVIEW

## Global Pharmaceutical Spend 2000-2015



## Top 10 Pharmaceutical Firms 2010-2016

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

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





# COMPETITION ISSUES:

- Competition issues arise in these markets through various conduct including:
- **Excessive pricing**
  - ❖ Pricing in pharmaceutical markets is complex due many factors such as price setting through sector regulators, intellectual property rights which engenders innovation, cost estimations of the manufacturing of medicines
- **Pay-for-delay**
  - ❖ *“...encompass[es] 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.”* (Report from the Commission to the Council and the European Parliament on Competition Enforcement in the Pharmaceutical Sector (2009-2017))
- **Funding and facilities**
  - ❖ Non-pricing related concerns arise in the value chain of healthcare e.g. information asymmetries which inhibits choice, unequal bargaining power between hospitals and medical insurance/funders, mergers and acquisitions, abuse of dominance





## Pricing investigations into pharmaceutical markets

- **Italy** – imposed a EUR 5.2 million fine on Aspen for abusing its dominant position by setting unfair prices for off-patent cancer medicines (Leukeran, Alkeran, Purinethol and Tioguanine)
- **United Kingdom** – found that Pfizer and Flynn abused their dominant position by imposing unfair prices for phenytoin sodium capsules (epilepsy medicine)
- **EU-wide investigation** – against Aspen Pharma relating to unfair pricing concerning cancer medicines
- **India** – Investigation against Roche for alleged anti-competitive conduct regarding the cancer drug, Trastuzumab
- **Denmark** – investigation into the out-of-patent drug Syntocinon used by pregnant women. CD Pharma had an exclusive distribution agreement with the producer of Syntocinon. Amgros (wholesale buyer for hospitals) put out a tender on Syntocinon which was won by a parallel importer but this firm was unable to provide the full amount to Amgros due to the exclusive agreement. CD Pharma increased the price of the drug by 2,000% which the Danish Competition Authority ruled that CD Pharma's price increase amounted to an abuse of a dominant position
- **South Africa** – investigation of excessive pricing against Roche and Genentech relating to the drug Trastuzumab, sold under Roche's brand names, Herceptin and Herclon for the treatment of breast cancer



## Pay-for-delay

- **Johnson & Johnson case**

- ❖ Developed fentanyl, a patch painkiller used by cancer patients
- ❖ 2005 the patent expired in the Netherlands and Sandoz (Novartis) was due to launch its generic fentanyl patch
- ❖ July 2005 Sandoz and J&J concluded a 'co-promotion agreement' where Sandoz was precluded from entering the Dutch market in return for monthly payments calculated to exceed the profits Sandoz expected to obtain from selling its generic product.
- ❖ J&J was fined EUR 10.8 million and Sandoz (Novartis) was fined EUR 5.5 million

- **Teva case**

- ❖ US FTC reached a global settlement with Teva Pharmaceuticals Industries Ltd
- ❖ If approved it would prohibit Teva from engaging in reverse-payment patent settlement agreements that impede consumer access to lower-priced generic drugs including (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



## Funding and facilities

- **Information asymmetry** makes it difficult for consumers to assess prices, quality and the necessity of various forms of care
- **Unequal bargaining power** – 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 overall healthcare expenditure – this can be resolved by granting exemptions to conduct such as collective bargaining (e.g. price setting) to mitigate for the unequal bargaining power of hospital groups or insurers
- **“Creeping mergers”** particularly in hospital markets has the potential to lead to increased levels of concentration. Merger regulation therefore becomes a significant tool available to competition authorities in considering access to healthcare services and reducing associated costs



- WTO-TRIPS provides for minimum protections of IPRs especially in relation to patents
- There are some flexibilities afforded by TRIPS including adoption of measures necessary to protect public health e.g. compulsory licencing
- Flexibilities have not been used in relation to pharmaceuticals and concerns relating to access and the affordability of healthcare and medicines

## Examples of WTO cases relating to TRIPs and pharmaceuticals

- Examples indicative of instances where there are allegations of sufficient domestic patent protection:
  - ❖ India – WT/DS50/IB/R
  - ❖ India – WT/DS79/R
  - ❖ Argentina – WT/DS171/R (1999)
  - ❖ Pakistan – WT/DS36/R
- Still scope for countries, especially developing countries to take advantage of TRIPS flexibilities



# CONCLUSION AND RECOMMENDATIONS

- Healthcare must continue to be a priority to policy-makers, sector regulators and competition law regulators
- **Policy-makers:**
  - ❖ Pursue and advocate for enabling policies for increased government expenditure in health services
  - ❖ Promote innovation in pharmaceuticals
  - ❖ Take advantage of TRIPS flexibilities
- **Sector regulators:**
  - ❖ Ensure transparency and adequate regulation in the pharmaceuticals and healthcare markets
- **Competition regulators:**
  - ❖ Prioritise competition issues in pharmaceuticals and healthcare markets (e.g. medicine pricing, pay-for-delay)
  - ❖ Cooperation among competition regulators will enable better and effective enforcement
- Competition regulators have an essential role to play in the ecosystem of ensuring that pricing of healthcare remains affordable





**END**

**THANK YOU**

