An industry perspective on access to medicines

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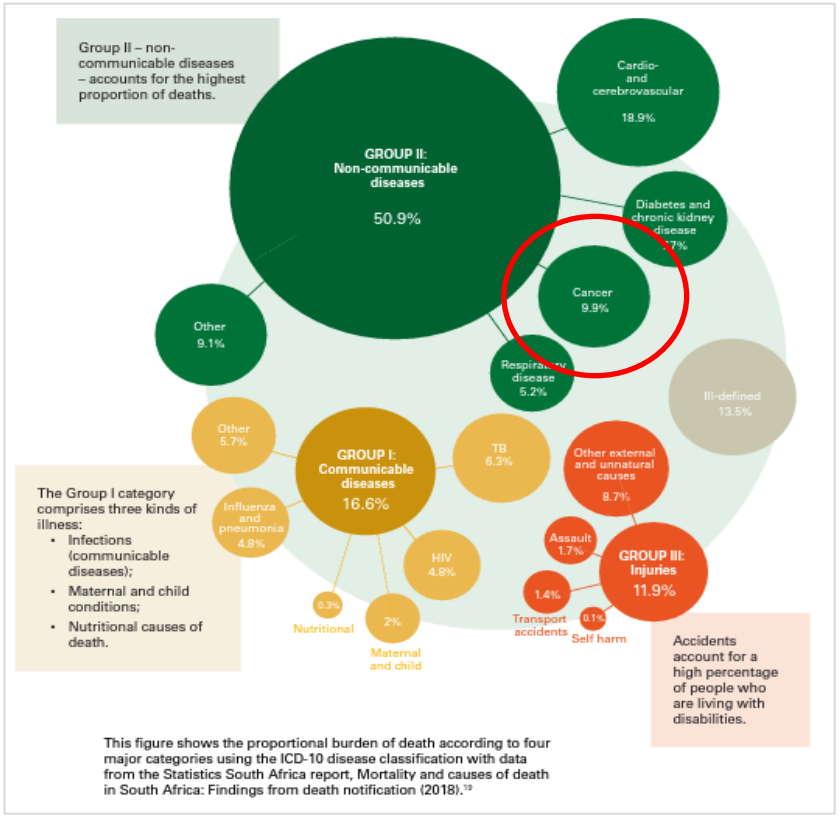
IPASA
Innovative Pharmaceutical Association South Africa

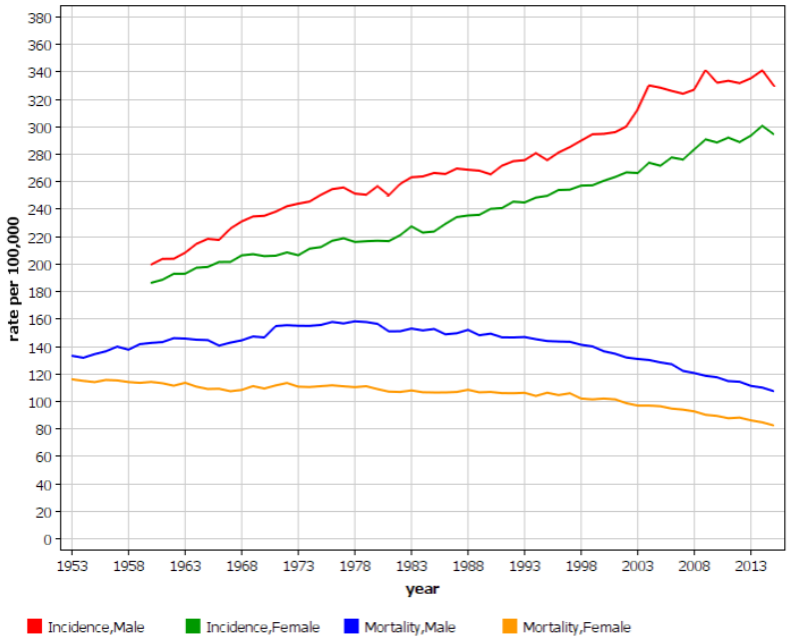
The rise of NCDs in SA

The WHO estimates the burden of NCDs to be 2 to 3 times higher in SA than in high income countries.



- NCDs pose some of the greatest threats to health and development, particularly in LMICs.
- Advances in treatment options have increased life expectancy of people living with communicable diseases like HIV and TB, and many are developing NCDs.
- In South Africa, NCDs are a leading cause of death and disability, outpacing communicable diseases by more than 30%.
- Cancer accounts for 9.9% of NCD mortality and whilst mortality data for other rare diseases is not available, about 3.6 million people are living with a rare disease.
- Unlike other NCDs, treatment options for ***cancer and rare diseases are limited and likely to carry a higher cost*** resulting in access challenges.

While there are more Cancer cases – fewer people die of Cancer

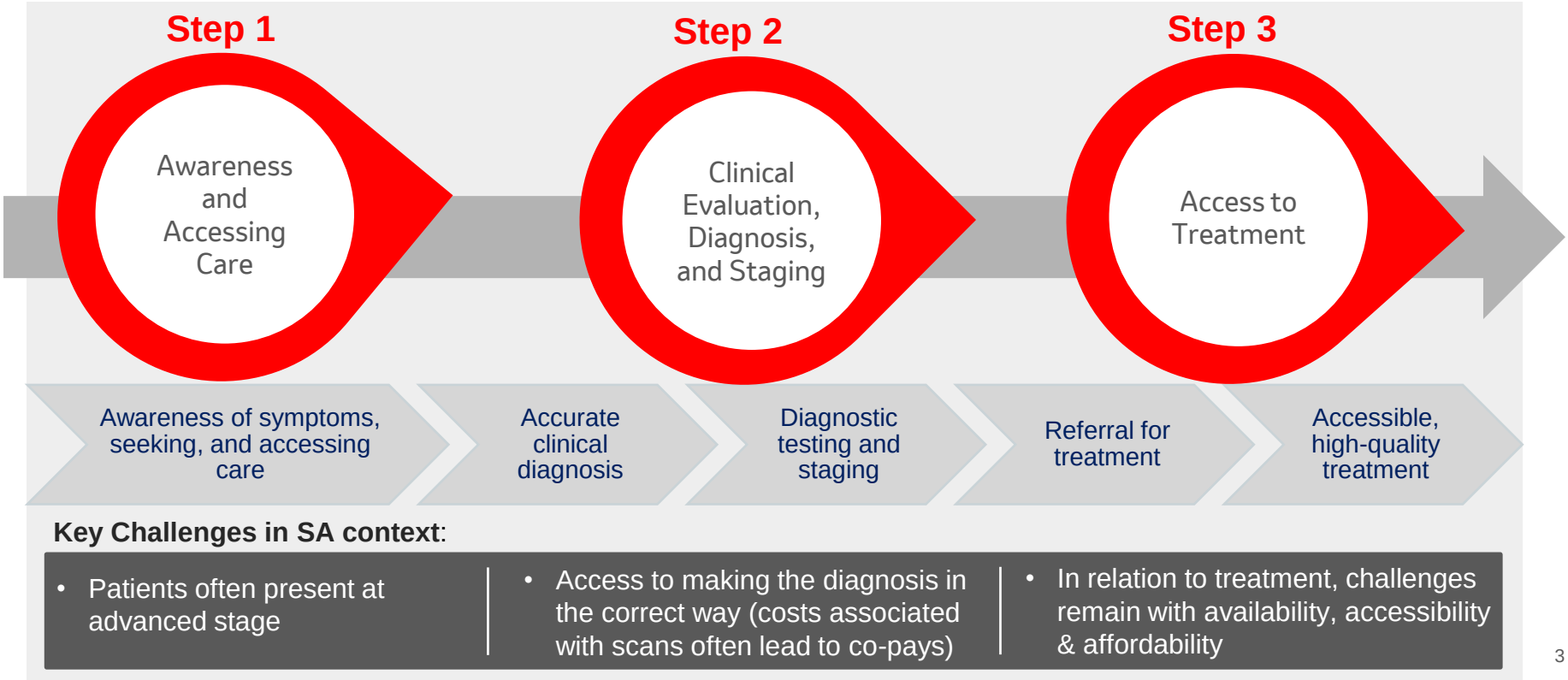


NORDCAN © Association of the Nordic Cancer Registries (4.11.2018)

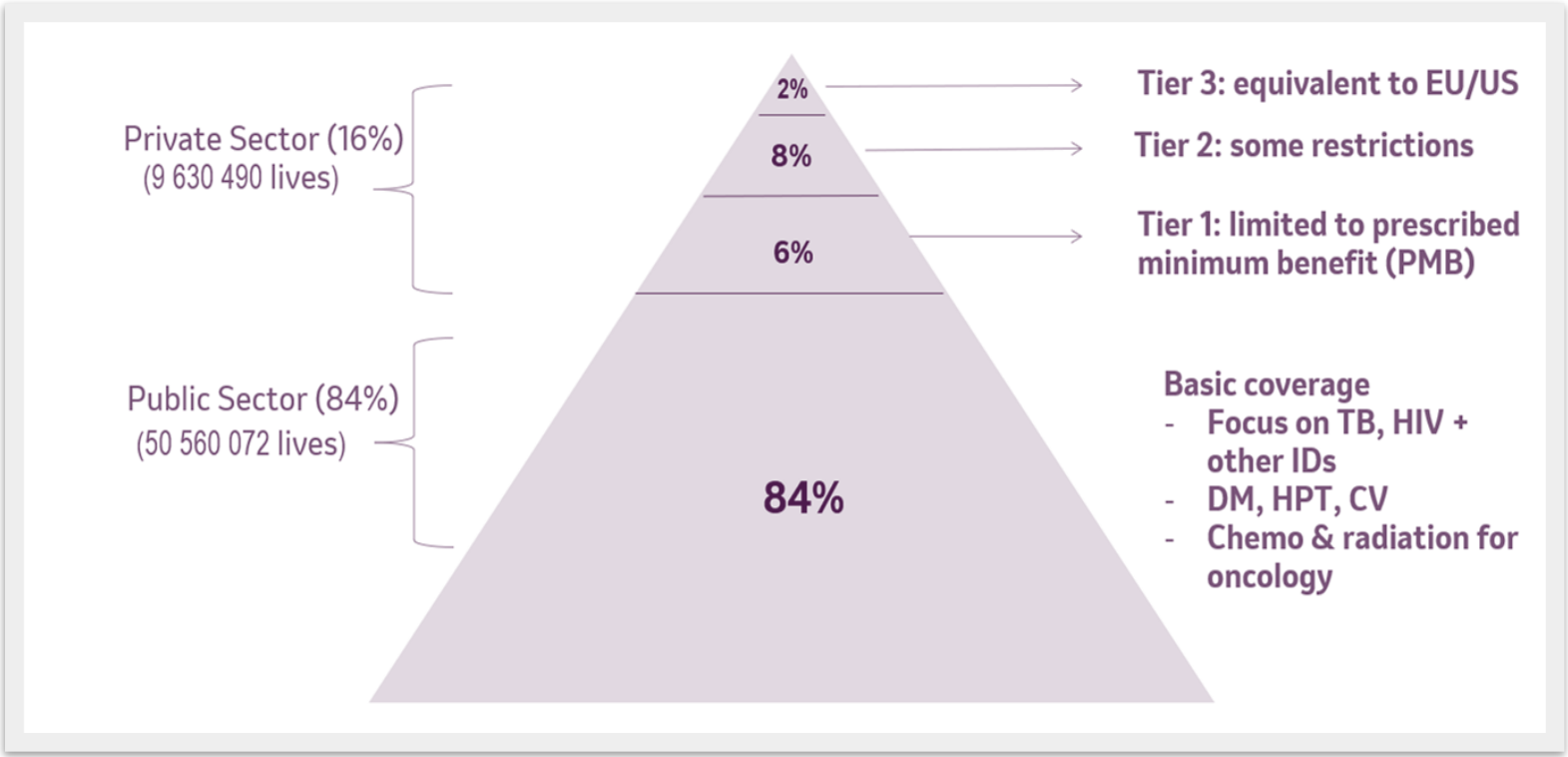
- Despite increasing incidence of cancer, there is decreasing mortality thanks to advances in prevention, screening, diagnosis and treatment [1]
- Cancer is set to become disease burden #1. There will be even more people with cancer in the future due to demographic change and lifestyle [1]
- There will be more treatment options in the future: In 1996, a physician had only 4 medicines to treat lung cancer. In 2016 there were 19 different medicines available [2]
- Lung cancer was the last killer. 20years ago a lung cancer diagnosis was considered a death sentence. Since then, the five-year lung cancer survival rate has increased by 15-30% globally – largely due to immunotherapies

Sources: [1] Jönsson B et al. (2016), Comparator Report on Patient Access to Cancer Medicines in Europe Revisited; http://ihe.se/en/publicering/cancer-medicines-in-europe-2/;
[2] IQVIA Institute (2017), Global Oncology Trends 2017; https://www.iqvia.com/institute/reports/global-oncology-trends-2017-advances-complexity-and-cost

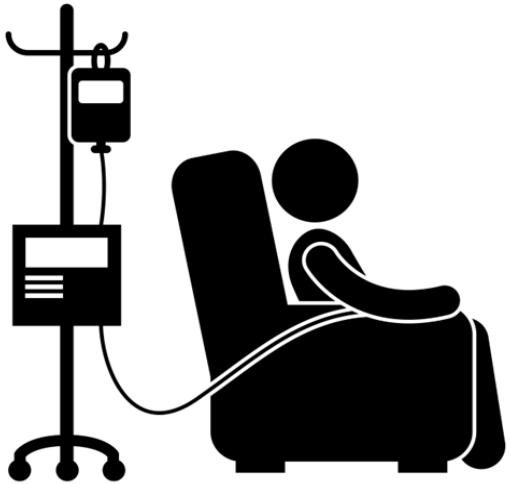
Timely patient access to the continuum of care remains a challenge



The South African Healthcare landscape illustrating the disparities in terms of level of care



Describing the patient affordability challenge in SA



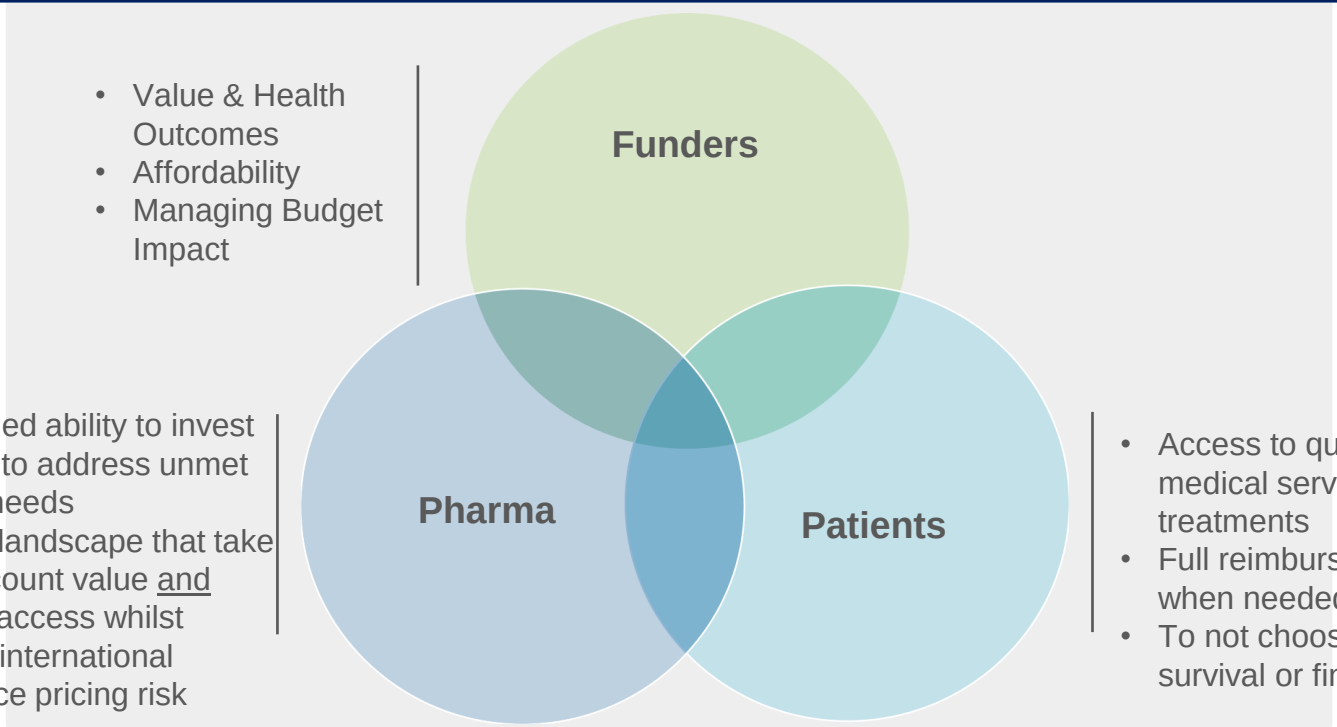
Meet Karen

- Karen has had top-tier medical aid for over 20 years (tier 3).
- She has been diagnosed with late-stage lung cancer and her oncologist has prescribed an immuno-therapy
- Her plan will only cover 80-75% of the prescribed therapy and Karen will have to cover the additional 20-25% out-of-pocket
- This could equate to a payment of R18,000-R25,000 every 3 weeks for approx. 35 treatment cycles (R 875 000)
- Whilst she may have some savings and investments to tap into, Karen will likely not be able to sustain the co-payment, and as a result, will likely cease treatment, undermining potential clinical outcomes

Karen represents ~9% of the insured population with some cover for innovative therapies. Approx. 91% of the insured population is completely excluded from receiving innovative oncology therapies

Enabling affordable access to innovative medicines in a financially sustainable manner – a delicate balance

SEP = Legislated nett price transparency + no discounts, rebates or bonusing (i.e. ARMs) allowed in private market



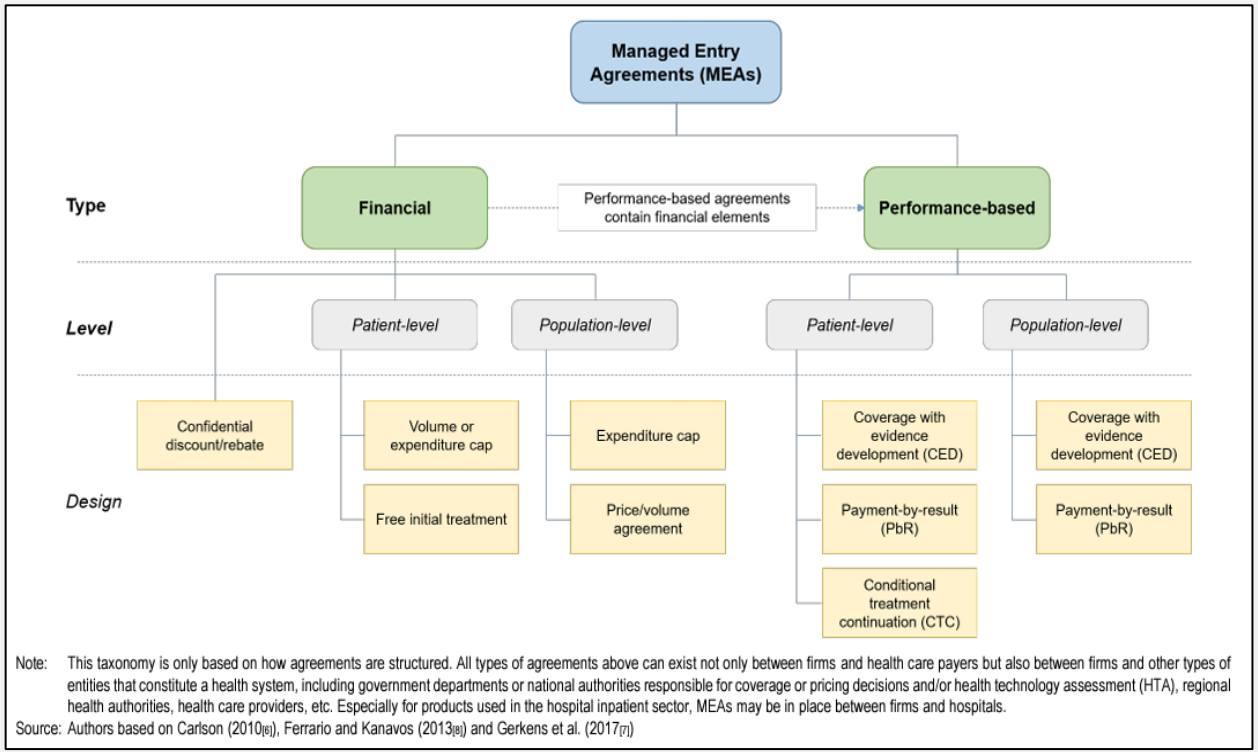
- Value & Health Outcomes
- Affordability
- Managing Budget Impact

- Continued ability to invest in R&D to address unmet health needs
- Pricing landscape that take into account value and patient access whilst limiting international reference pricing risk

- Access to quality medical services and treatments
- Full reimbursement when needed
- To not choose between survival or financial ruin

Defining Alternative Reimbursement Models (ARMs)

ARMs should be designed with the aim to improve patient access and clinical outcomes.



Note: This taxonomy is only based on how agreements are structured. All types of agreements above can exist not only between firms and health care payers but also between firms and other types of entities that constitute a health system, including government departments or national authorities responsible for coverage or pricing decisions and/or health technology assessment (HTA), regional health authorities, health care providers, etc. Especially for products used in the hospital inpatient sector, MEAs may be in place between firms and hospitals.

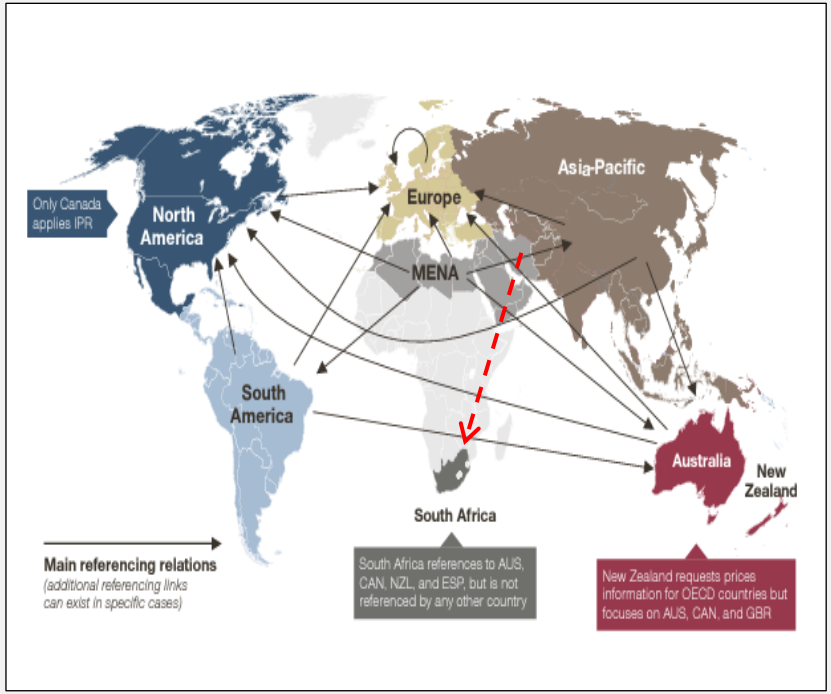
Source: Authors based on Carlson (2010[6]), Ferrario and Kanavos (2013[8]) and Gerkens et al. (2017[7])

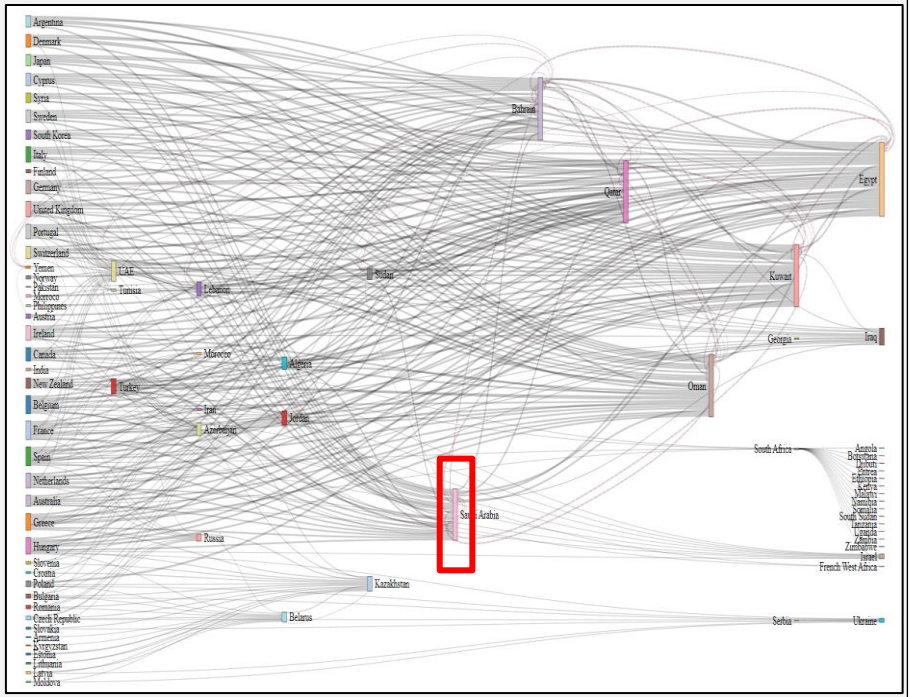
Practical Examples:

- Funder reimburses product x at 100%.If product fails to achieve intended clinical outcome, manufacturer can provide partial or full refund (rebate) to funder
- On the basis of guaranteed volumes over set period, funders negotiate a discount with manufacturers (e.g. SA EPI)
- On the basis of volume over a period of time, funders negotiate a utilisation cap and sales which exceed agreed volume are provided free of charge (FOC).

Why not simply reduce price…?

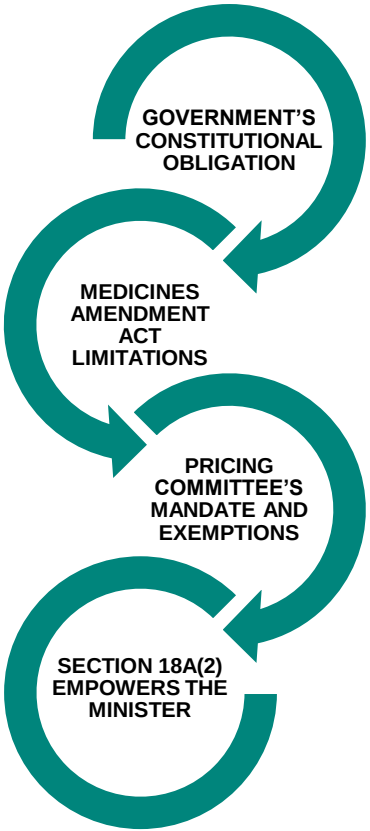
South Africa is the only country globally with net price transparency and ease of inter-country visibility





The implication of this is that when pricing for South Africa, **because SEP legislation requires transparency and is easily accessible to other countries**, manufacturers have to take into consideration the potential ramifications of South African pricing in other key markets.

The South African legislative & policy framework



- The **Constitution** charges Government to take reasonable measures, within its available resources, to ensure the progressive realisation of health rights.
- **Pillar 2** of the Presidential Health Compact calls on all signatories to promote access to innovation, amongst other priorities. (Specifically, user groups to recommend options for innovative access models)

- **Section 18A** of the Medicines Amendment Act prohibits supply of medicines according to a bonus system, rebate system or any other incentive scheme.
- Furthermore, **Section 22G** stipulates that a single exit price shall be published as prescribed, and such price shall be the only price at which manufacturers shall sell medicines and Scheduled substances to any person **other than the State**.

- **Section 36(2)** of the Medicines Act gives the Pricing Committee the powers to recommend which medicines may be excluded from Section18A (bonussing/ sampling & incentives) and 22G (SEP/Transparency) for the Minister's approval.

- **Notwithstanding Section 18A(1),** the Minister of Health may prescribe acceptable and prohibited acts in relation to subsection (1) in consultation with the Pricing Committee referred to in section 22G."
- Section 18A(2) enables the establishment of new regulations which could define conditions under which ARMs could be utilised to expand patient access to innovative medicines.

Our position – in a nutshell

SEP is important but has limitations for expanding patient access to innovation

- For conditions where there are multiple effective treatment options, SEP can play a meaningful role in protecting consumers from unnecessarily high medicines costs
- However, for conditions where effective treatment options are limited (e.g. certain cancers and rare diseases) SEP has resulted in unintended consequences for patient access due to its restrictive nature

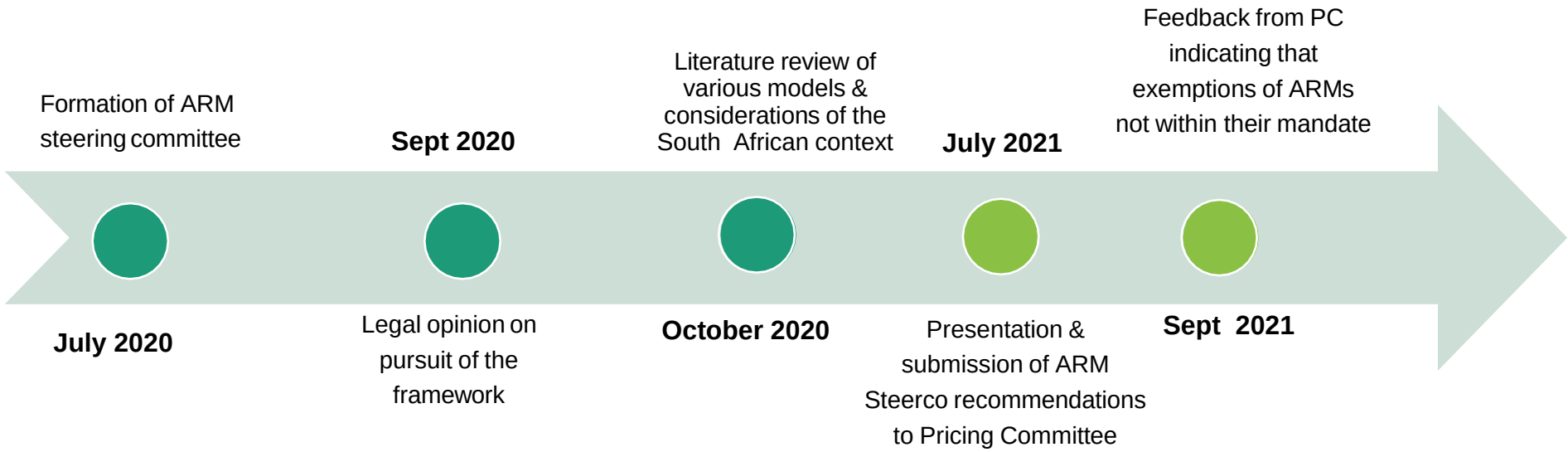
Transparency of the pricing process is not the same as net price visibility which limits access, esp. for LMICs

- Transparency of the price setting process is important as it supports good governance and ensures accountability of all parties.
- ARMs can be achieved with transparency among relevant in-country stakeholders whilst limiting inter-country visibility.

A mechanism for approval of ARMs on an exemptions basis should be established to promote patient access to life saving treatments

- ARMs should only be applicable on an exemption basis for conditions where there are limited treatment options.
- Guiding principles should be based on clinical need, equitable access for patients, and equal treatment of all funders.
- A predictable governance framework should be established to empower the Pricing Committee to make recommendations in this regard for the Minister's approval as articulated in S36
- As a start, a small number of proposed ARMs could be selected as pilots to enable additional learning, as we move towards the NHI.

Industry efforts to date



ARM STEERCO MEMBERS

- **Agility Health Holdings (Pty) Ltd.**
- **Board of Healthcare Funders (BHF)**
- **Campaigning for Cancer NPC**
- **Health Funders Association (HFA)**
- **Innovative Pharmaceutical Association South Africa (IPASA)**
- **Presidential Compact's Health Service Users Grouping**
- **Pharmaceutical Task Group (PTG)**
- **Rare Diseases South Africa (RDSA)**
- **South African Medical Association (SAMA)**

Thank you

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