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Innovative Patient Access Schemes to New Pharmaceuticals for the Elderly

Kenneth KC Lee

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Innovative Patient Access Schemes to New Pharmaceuticals for the Elderly

Outline of presentation

- Current Challenges
- Innovative Patient Access Schemes (IPAS)

Current Challenges

- Healthcare systems aspire to provide **accessible**, **effective** and **efficient** healthcare services for all individuals living in any given country.

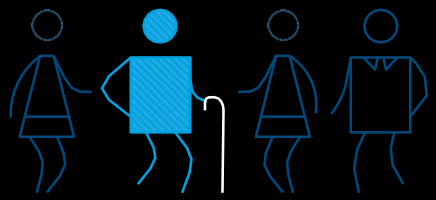
- Attaining these objectives are increasingly challenging: financial constraints, **aging population**, increasing demand for better coverage, rising expectations, rapidly emerging new technologies alongside scientific advances, and cost of delivering care.

- Given the upward pressure on the global health budget, balancing total spend on pharmaceuticals with the imperative to provide timely access to new medicines will be a critical priority for policy-makers.

The pharma market access and pricing environment in Europe is rapidly changing

Payers are responding to:

Aging populations



By **2030** 25% of the European Union's (EU) population will be aged **65 and over**, up from **19% in 2015**.

Chronic diseases

From **2018** and **2040** the incidence of **cancer** is predicted to increase by 23%.

From **2017** and **2045** the number of people with **diabetes** (aged 20-79) is projected to increase by 16%.

*Constrained health care budgets are impacting pharma spending**

GDP spent on the **health care** has increased from **9.52%** in **2010** to 9.74% in 2016

GDP spent on the **pharmaceuticals** has decreased from **1.50%** in **2010** to 1.36% in 2016

Increasing pressure to fund drugs for rare diseases

From 2007 to 2017:

- the **EMA** has given 1544 orphan drug designations
- the **FDA** has given 2707 orphan drug designations.

Worldwide, it is estimated that **orphan drug sales** will total $216 billion by **2022**, up from **$125 billion** in **2017**.

Governments in Europe have tightened policy towards reimbursement and pricing

2:1 ratio of **unfavorable** to **favorable** policies.

Note:* 16 European countries were included in this analysis; Austria, Belgium, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Norway, Poland, Portugal, Spain, Sweden, Switzerland and The UK.

Drug Formulary Access – a step to ensure patient's access

For patients, the formulary can determine which drugs are **available**

for treatment.

For payers, the formulary will have a role in **determining the portion**

of total health care expenditures attributable to drugs, and may also

have an impact on total healthcare costs.

For manufacturers, formulary access can determine whether there

will be any **revenue** generated from their products.

FORMULARY ACCESS

Risk and Uncertainty of formulary decisions

- Payers still face considerable risk and uncertainties when adding new products to a formulary.

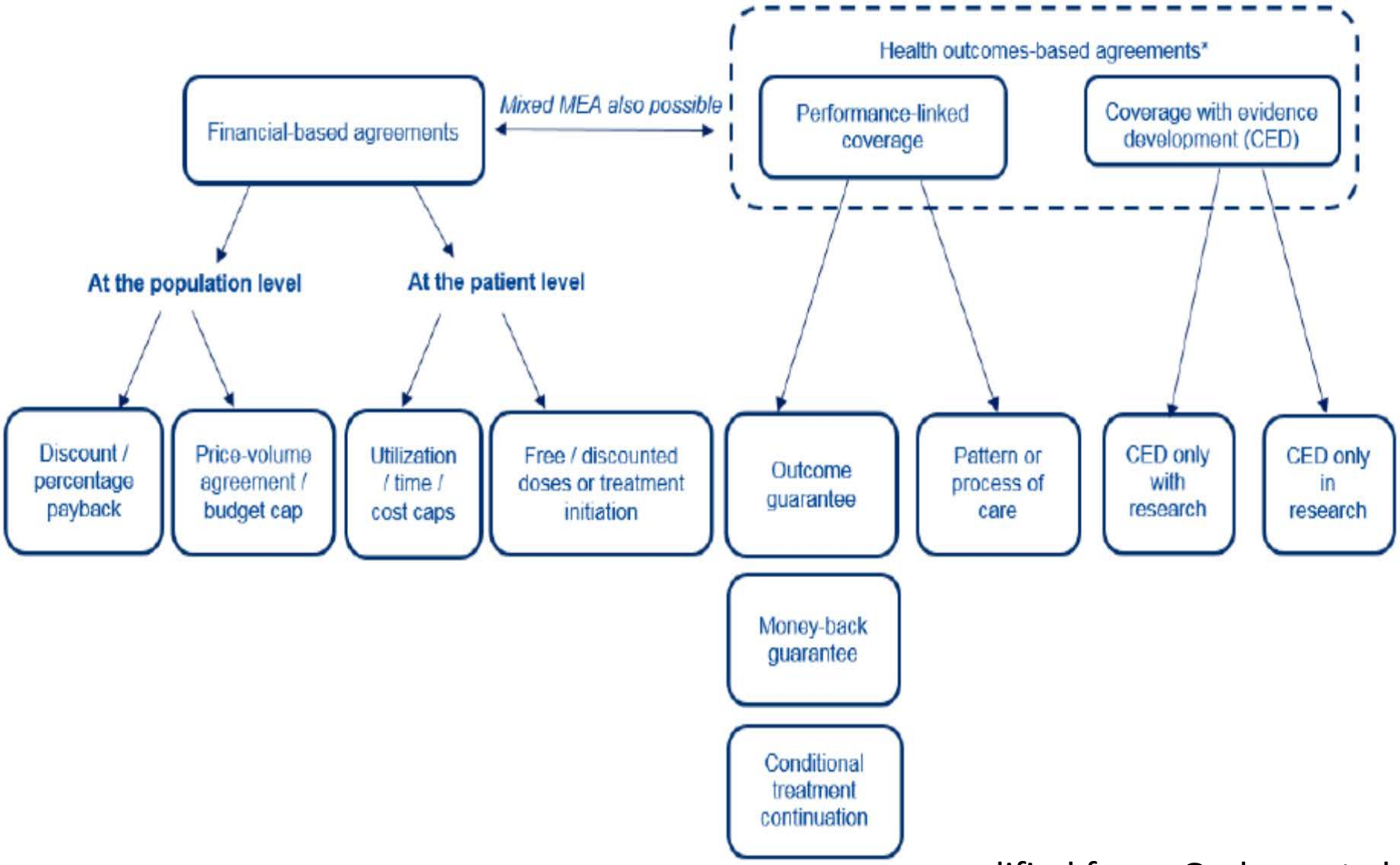
  - the effectiveness of a drug in real-world use may be less; the drug may have a less favorable cost-effectiveness ratio; and demand may be much greater than anticipated.

(Zaric, Zhang, & Mahjoub, 2013))

- The pressures faced by payers and manufacturers have led to the **innovative patient access schemes (IPAS)** for new medicines, which led to development of contracts between payers and pharmaceutical manufacturers.

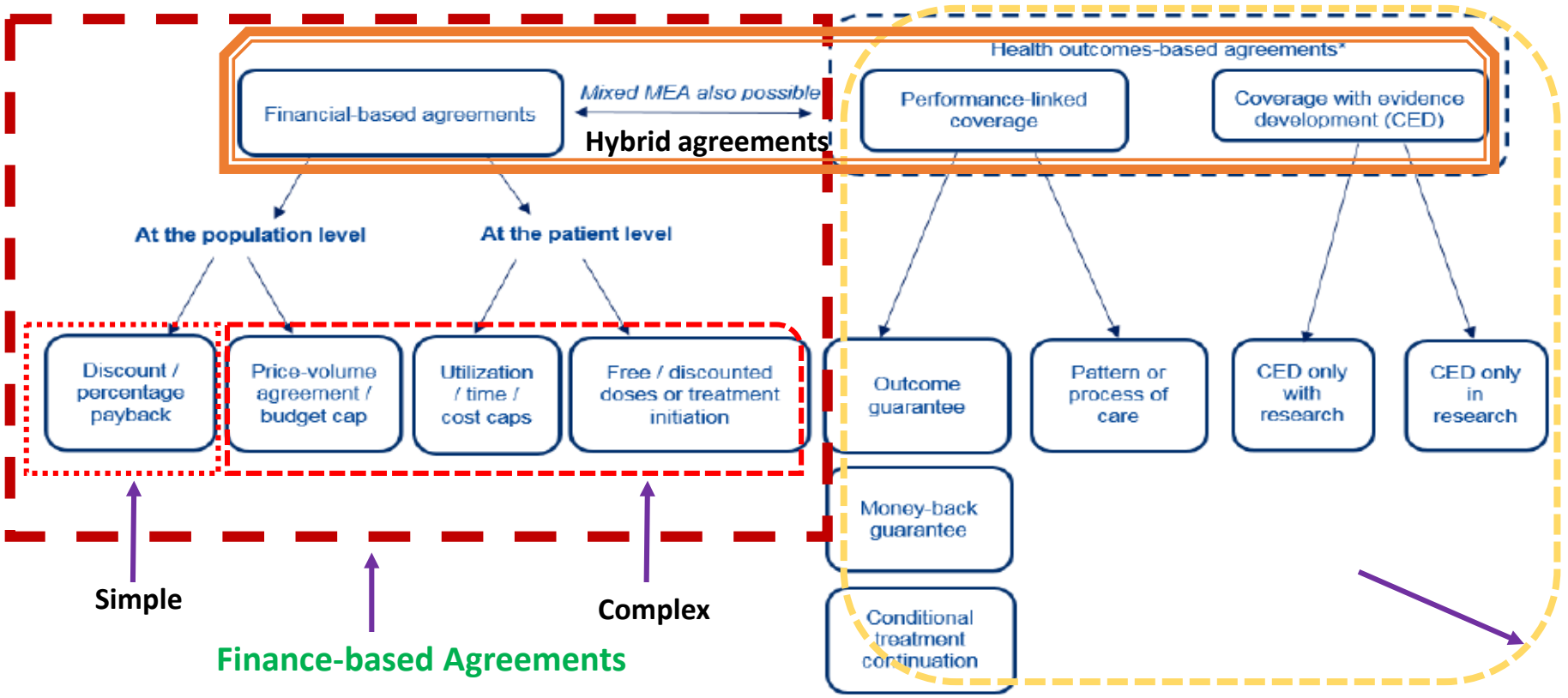
(Garrison et al., 2013)

Taxonomy of innovative patient access schemes



modified from Gerkens et al. 2017)

Taxonomy of innovative patient access schemes



(modified from Gerkens et al. 2017)

Finance based schemes

- Price Cap

  Italy - Bevacizumab for the management of approved cancers cannot exceed €25,941 per year

  Sweden - Stockholm County Council initially signed an agreement in April 2008 lasting until end December 2009 whereby if patients with advanced cancer exceeded an accumulated dose of 10,000 mg of bevacizumab, the additional costs would be fully covered by the company

- Price Volume Cap

  Has been in place for a number of years in Australia with price reductions if sales exceed a subsidized cap or threshold.

Finance based schemes

Free Drugs

- Sunitinib for patients with metastatic renal cell carcinoma. Under this scheme, the first treatment cycle (6-weeks costing an average of GB £ 3139/patient) is provided free via a patient access programme. Subsequent cycles are funded by the NHS-UK.

Performance-based schemes

Outcomes guaranteed

- Sandoz Canada promised to reimburse individuals, hospitals and government drug plans where patients with treatment-resistant schizophrenia discontinued clozapine within six months.
- This was initiated to address acquisition cost concerns versus typical anti-psychotics among the Provinces.

Finance/ Performance based schemes (Italy)

Drug	Indication	Type of scheme
Sorafenib	Hepatocarcinoma	Payment by result
Denosumab	Skeletal related events in adults with bone metastases from solid tumors	Cost Cap
Bortezomib	Multiple Myeloma	Discount
Ipilimumab	Advanced melanoma	Payment by result + Cost Cap
Erlotinib	NSCLC	Cost Sharing + Cost Cap

Walzer S et al. 2015

Coverage with evidence development (New)

- UK Multiple Sclerosis Risk-Sharing Scheme (MSRSS). This scheme was set up by the Department of Health after negative NICE guidance for the drugs (interferon beta and glatiramer acetate). The idea behind the scheme was to develop more evidence and to improve cost effectiveness.

PAS in Asia Pacific by type & condition

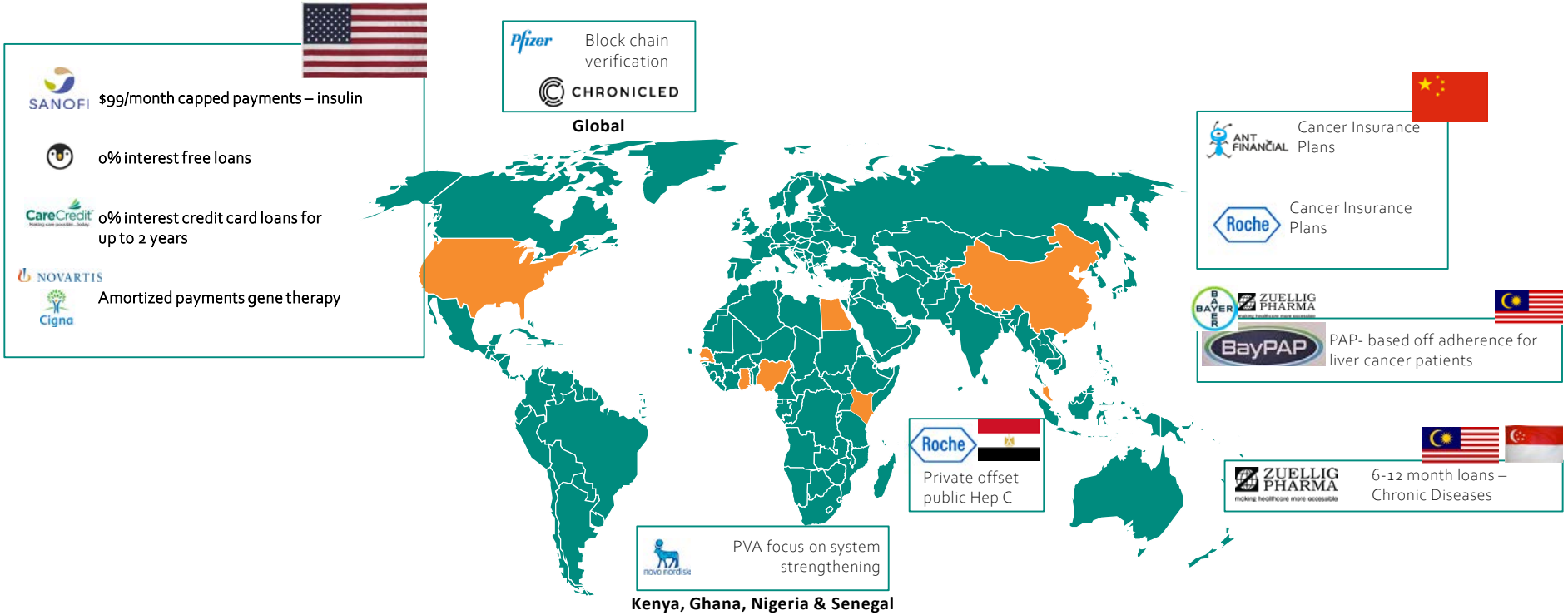
	Australia	South Korea	New Zealand	Total
Types				
Outcome-based	21	-	-	21
Evidence generation	3	-	-	3
Financially-based	33	3	5	41
Hybrid*	41	-	-	41
Conditions				
Cancer	29	-	2	31
Inflammatory Conditions	28	-	1	29
Infectious Disease	7	-	-	7
Pulmonary Hypertension	7	1	1	9
Other	27	2	1	30
Technology				
Pharmaceuticals	95	3	5	103
Medical devices	3	-	-	3
Subtotal	98	3	5	106

*Hybrid schemes involved both pricing arrangements and conditional treatment continuation

- About 77% schemes involved pricing arrangements in Asia-Pacific
- Hybrid arrangements: consisting of both pricing and performance components (Lu et al 2015)

Lu et al. Journal of Pharmaceutical Policy and Practice (2015) 8:6
DOI 10.1186/s40545-014-0019-x

Examples of Innovative private health Insurance and financial solutions



Not exhaustive

Source: Mukherjee MSD 2019

Potential benefits of IPAS

- Improve patient access to medicines which are likely to have high budget impact
- Provide access to innovative care within finite budgets.
- Address the rising cost pressure, consumer demands and uncertainties

Concerns of IPAS

- Health care cost is always on the rise
- Health care budget is always finite
- Patient number is usually increasing with time
- Sustainability can be a problem
- Alternative sources of financing healthcare is imminent

Summary of messages

- Elderly's early access to new pharmaceuticals must be attended to
- New IPAS are available in most parts of the world
- IPAS have advantages but concerns also need to be addressed
- If properly implemented, IPAS can lead to an "All Win" for patient, government and manufacturer

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