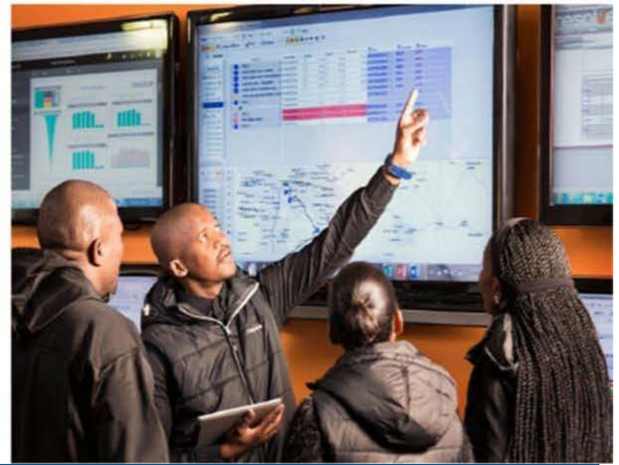






"Unintended Consequences and Hidden Obstacles in Medicine Access"

GHSC 2017
Accra

Dr Iain Barton

Imperial™ logistics

Regulating For Access To Medicines …

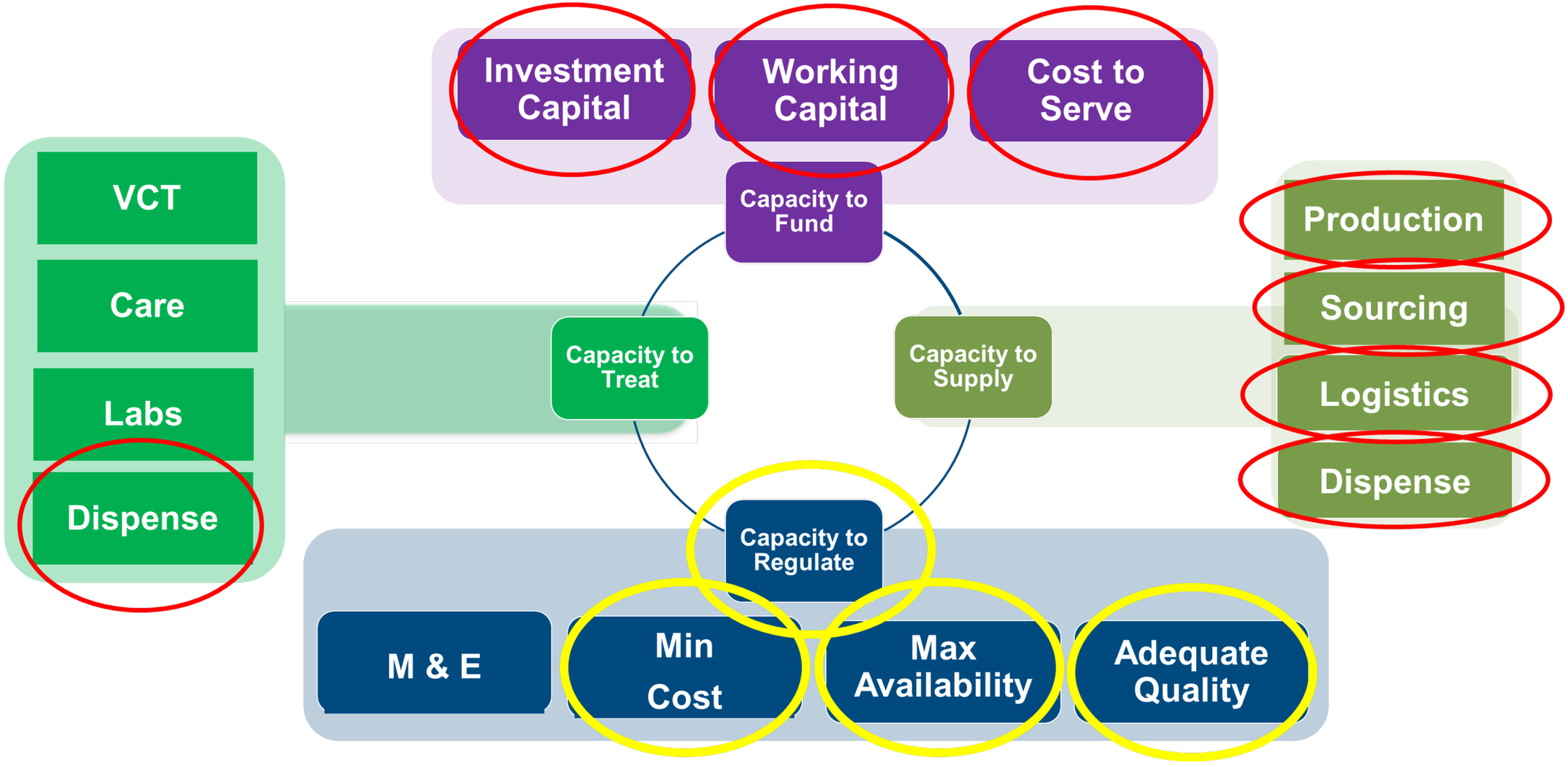
The narrow vision …

- Access to affordable, quality essential medicines is an inalienable human right
- Governments and their regulatory agencies are accountable for ensuring those rights
- A Drug Regulatory Authority's role is to ensure the safety quality and efficacy of medicines

BUT ….

- Actions and performance of Regulators have many other broad and significant impacts on:
  - Issues of access and affordability
  - Current approaches in enforcing regulatory controls at national / country levels:
    - Negatively impact patient care and the cost thereof
    - Even *FAIL* to ensure the quality of products in the market

The pillars of strength in a healthcare system



Our Sad African Reality

A market of great potential - $2.4tn … 33% higher than India

Over one billion consumers

Attractive rates of economic growth

BUT …

Landmass = 10 X India … 3.5 X China

54 discreet states

4 have populations > UK

18 < Wales

Economically … In nominal GDP listings …

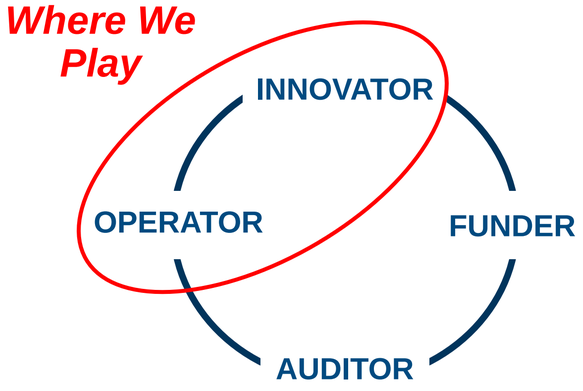
… first African country appears at 21

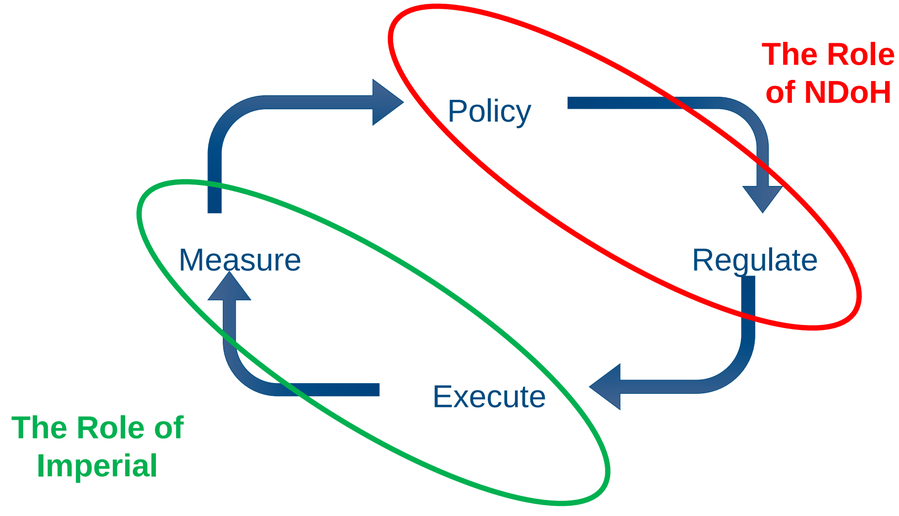
… only 14 make it into the top 100

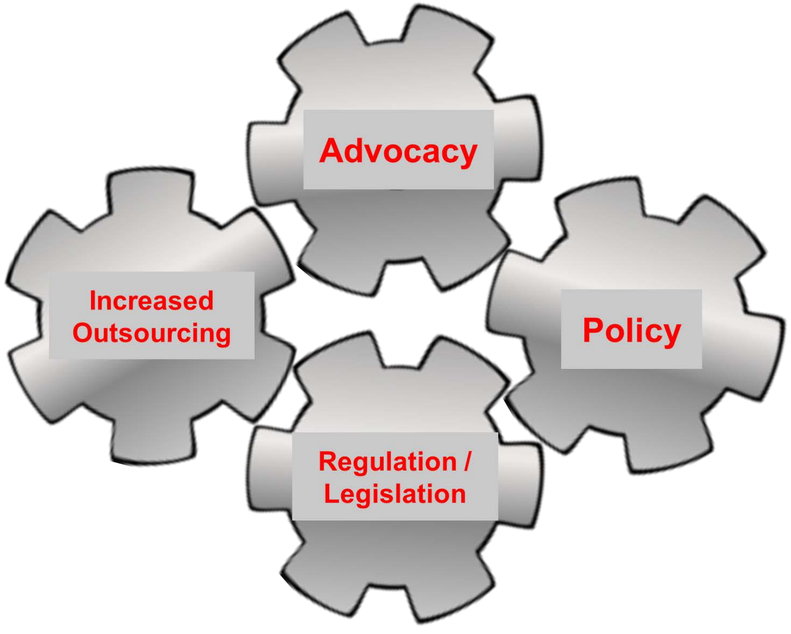
… African countries make up 40 of the poorest 90 countries in the world

"Lets encourage (and even incentivise with development aid) each tiny fragment to develop its own drug regulatory authority"

The Virtuous Cycles of our world







Impact On Availability

- Direct and indirect costs of registration and post-marketing support
  - Demand markets of scale for products to be viable
  - Limit the ability to achieve ROI for new products in small markets
  - Worst for lower cost / smaller margin products … so the poor are the most affected.

- Registration delays
  - Deprive patients of newer and more effective treatments
  - Drive medical tourism among the privileged few
  - Act as a disincentive for generic applications

- Local labelling requirements
  - Impossible to maintain reliable levels of fresh inventory
  - Extended stock outs or high levels of expiry

… On Affordability

- Direct Impact – Fact = 7 registrations per molecule = maximum impact on price
  - IMS data
    - Impact on price from multiple registrations of generics
    - Biosimilars - second third and fourth registrations drop price across entire therapeutic area
  - Expedited registrations reduce the price of healthcare faster than almost any other intervention

- Any wasted money gets worked into the price and the patient will pay
  - Registration costs, cost of capital, short runs for customised packing or stock expiries

- Supply chain costs
  - Small fragmented markets have no scale
  - Expensive to service
  - Require a higher margin per unit moved to achieve acceptable returns

… And On Quality Of Product

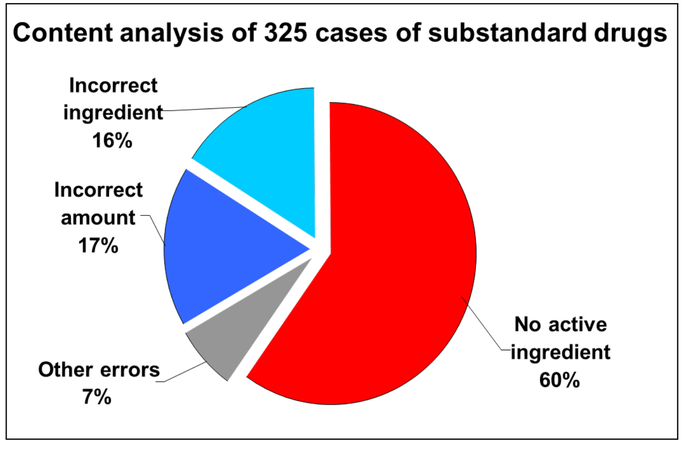
- It's NOT working
  - Substandard, grey, fake and counterfeit products abound
  - It's a highly profitable space with no policing and laughable penalties

- A strong case can be made that regulation is a *contributor causally*
  - Disincentivising quality partners to invest
  - Slowing the availability of product and
  - Increasing costs to the patients

"Up to 40% of the drugs in Africa …"
"36% of anti-malarials in SE Asia …"
"Trafficking fake meds makes 10X more profit than illicit drugs …"
www.fightthefakes.org

WHO _ SSFFC - substandard, spurious, falsely labelled, falsified and counterfeit

"The global counterfeit drug economy has been valued at US$75 bn a year, and is projected to grow by up to 13% annually"
Nature: 2012



The Residual Shelf Life Fiasco

Taking stupidity to a whole new level …

- Dumping of short-dated stock was a real issue … when?
- Expiry of valuable medicines was a real risk … why?
- But still the guidelines drive 80% / 85% residual shelf life at time of import

Shelf Life	2 year	3 year	4 year	5 year
Max Life	24 months	36 months	48 months	60 months
80%	19.25 months	2.5 years!!!	3.25 years!!!	4 years!!!
Post production QA	1 week			
Pre-shipment inspection	1 week			
Seafreight shipping	4 – 6 weeks			
Clearing	1 week			
Margin for error	10 weeks	3 months	> 6 months	> 9 months
Sarcastic barb(s) !	• Demands make to order • Forces direct drop ship / disallows any regional buffering • Drives up airfreight / cost • Go learn to forecast / plan better !!!		• How bad *is* your forecast ??? • What behavior are you driving in procurement cycle management ??? • Who has space to store product for 4 years ???	

- The world ***NEEDS*** a maximum of 18 months’ residual shelf life at time of import

But Stupidity Does Not Discriminate …

- Bill's Law of Stock Turns vs Capacity

Total pallets consumed per year = 10,000			
Procurement Cycle	Annual		
Targeted minimum stock held in months	6	9	12
Worst case stock turns per year	0.66	0.57	0.5
Pallet spaces required	15,150	17,500	20,000
And at 9% volume growth, pallet spaces required in 4 years	22,700	26,315	30,000

Total pallets consumed per year = 10,000			
STTA Intervention	Year 1	Year 2	Year 3
Procurement Cycle	Annual	6 monthly	3 monthly
Targeted minimum stock held in months	12	6	3
Worst case stock turns per year	0.5	1	2
Pallet spaces required	20,000	10,000	5,000
And at 9% volume growth, pallet spaces required in 4 years	30,000	15,000	7,500

Actual Stock Turns Per Annum today:

PFSA Ethiopia – 0.8

GSK East Africa - > 4

So What To Do?

- Stop teaching / promoting / incentivising / allowing this bull …

- Regulatory convergence / harmonisation
  - Simplifies registration, creates economic scale, extracts wasteful costs in production, registration, supply management and expiries, increases product availability, promotes competition and drives down prices
  - Drives / enables quality compliance
  - Long term - empowers regulators
    - Bigger combined market becomes a meaningful source of revenue
    - Managed markets enhance compliance

- Expedited processing for SRA approved products
  - Increased registrations, speedier access to innovations, quicker investor returns, increased product availability, more competition to drive down prices

For Quality …

- Big impact plays
  - ID and assay on imports / post-marketing surveillance / market sampling
  - Serialisation
  - Patient empowerment

- Policy and justice framework changes
  - The potential punishment must exceed the possible benefits
  - Policing, prosecutorial and judicial processes must work

- Support / incentivise local market investment and development
  - Create success … to establish something to lose

- Demands focus, resources and a willingness to fight the fight … among all stakeholders

What Is Being Done?

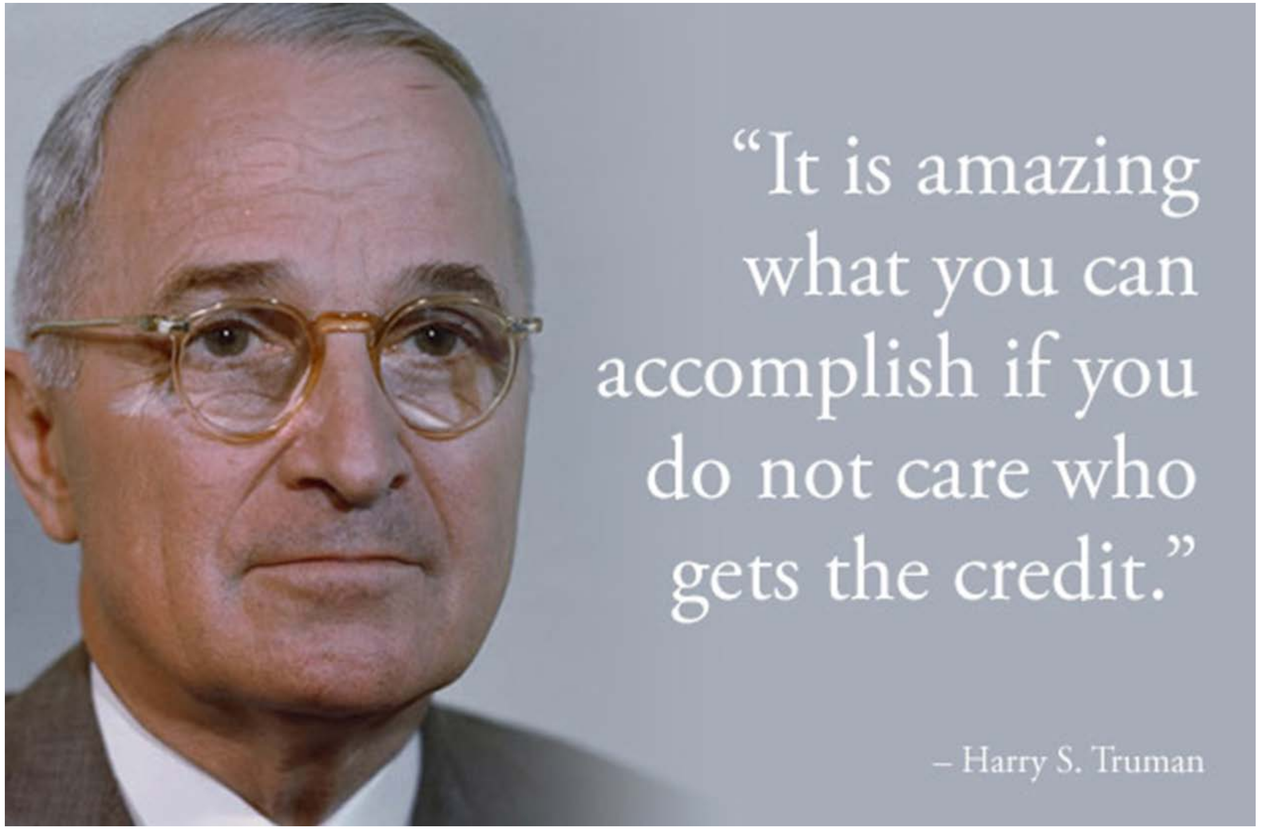
- Cell phone validation models
- Serialisation regulations
- Handheld devices using infrared light to authenticate

- Interpol’s Operation Pangea
  - Seized 2.4m packs in 2011 – 20.7m in 2015
- The Medicrime Convention – (2011)
  - Informal treaty to criminalize pharmaceutical fraud within countries’ borders

- East African Harmonisation project – Driven by BMGF (Gates Foundation)
- SADC Collaboration … with or without SA
- Fight The Fakes (www.fightthefakes.org)

My 85% Rule


“The power of the collective - working in the absence of ego – is insurmountable!”
Michelle Neilson


“It is amazing what you can accomplish if you do not care who gets the credit.”
– Harry S. Truman

Finally … A Bit Of Idealism …

- High availability of reputable brands at affordable prices makes life harder for the vendors of fakes and counterfeits

- Combined with strong post-marketing surveillance, rigid enforcement and punitive legal frameworks, a strong regulator has a real opportunity to influence the quality of product being delivered to patients

- Regulators ARE the good guys
  - Act now as a body so that you have control over the process and the outcome
  - This is becoming an irresistible force for change
  - It is far better for patients that the change is led by committed scientist than it is forced upon the market by “responsive” politicians

And one final thought …


That's all Folks!

Customise

Collaborate

Compete

Imperial™ logistics