

***Pharma & Device 2020 & the
Compliance Considerations***

***12th Annual Pharmaceutical
Regulatory and Compliance
Congress and Best Practices
Forum***

November 1, 2011

Our Vision for the Future - Pharma 2020 Series



Chronic diseases are putting healthcare expenditures under pressure

Cardiovascular disease (CVD)

- Today 16m people die from CVD
- Expect a 200% to 400% rise in
- CVD death toll could be 25 - 50

More people are living longer with chronic diseases which were previously fatal

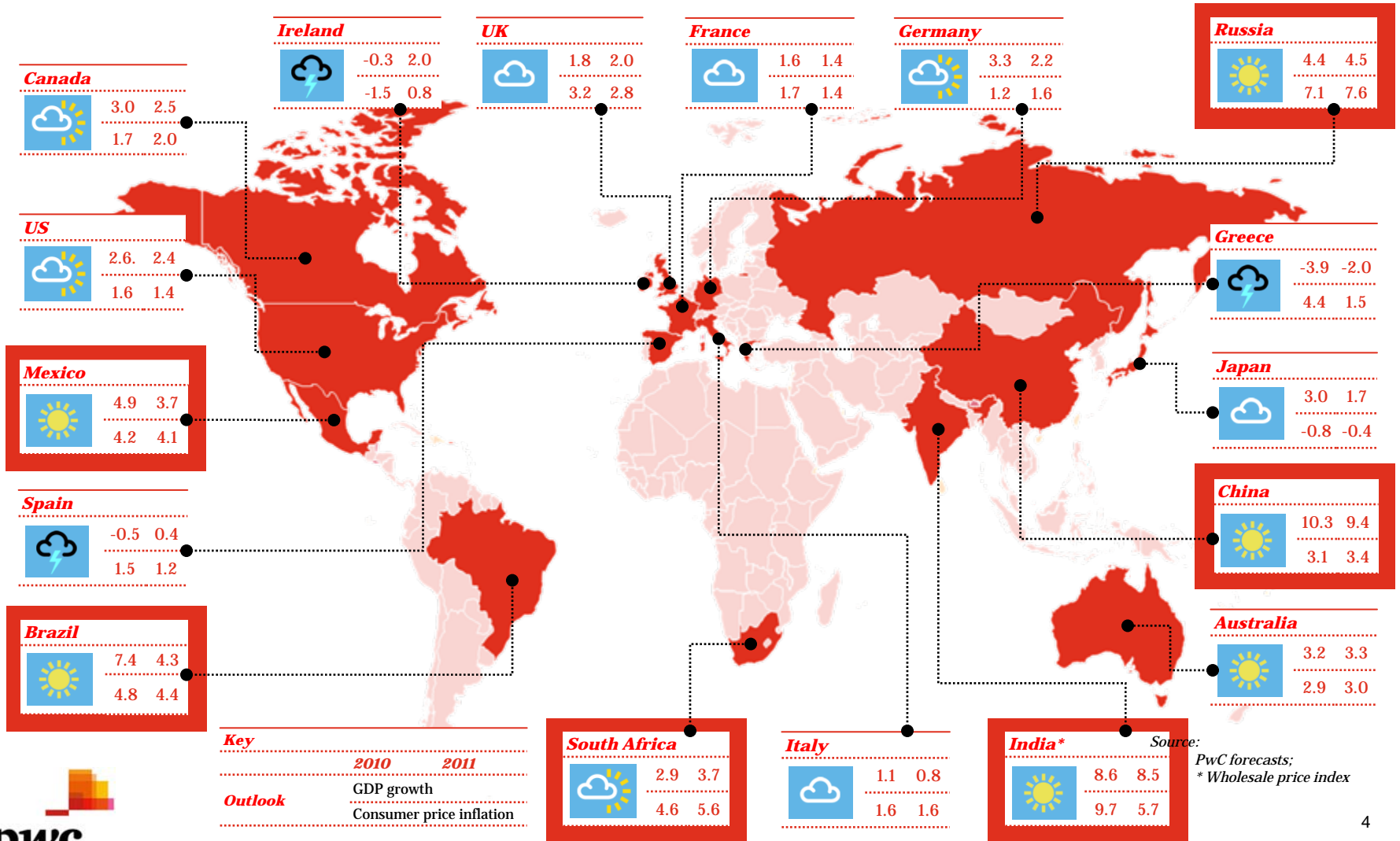
Hypertension

- Globally about 25% (>970m) of t
- 330m in developed countries: 610m in developing countries.
- >1.5bn cases of hypertension in 2025, most from developing countries.

Obesity and diabetes

- Today >1bn adults worldwide are overweight, 312m are obese.
- Projected increase in diabetes: 171m in 2000 to 366m by 2030 (214% increase).
- Developing countries diabetes is expected to increase from 84m to 228m.

Growth shifts east and pharma needs to respond..



...with specific strategies to maximise high growth

Growing economies and populations

Pressure to cut healthcare costs

Shift to “Western” diseases

Disposable incomes

Expansion of healthcare systems

- *Quick market access*
- *High generic penetration*
- *Branded off-patent drugs*
- *Fast growth of domestic generics players*
- *Low manufacturing and distribution costs*

Chronic disease bills are soaring

- Shift toward a pay-for-performance model requiring companies to obtain outcomes data from tech companies, providers, and payers.
- Different forms of care are being combined to deliver the best possible product package (e.g., device, diagnostics, drugs, exercise, preventative treatment, lifestyle changes, etc.)
- Industry will need to demonstrate real "value-for-money" with respect to its products
- "Innovation" is being redefined

Top 20, by Treatment Expenditures (\$bn) in 2015

Rank	Disease	Exp (\$b)
1	Diabetes and Obesity	56.0
2	Hypertension	51.7
3	Coronary heart disease	36.8
4	Depression (MDD)	22.9
5	Chronic kidney disease	21.8
6	Stroke	20.8
7	COPD	18.2
8	Asthma	16.9
9	Osteoarthritis	15.3
10	Breast cancer	10.7
11	Bipolar disorder	10.3
12	Congestive heart failure	9.1
13	Epilepsy	8.6
14	ADHD	7.3
15	Osteoporosis	5.5
16	Angina	5.4
17	Eating disorders	1.2
18	Chronic venous insufficiency	n/a
19	Alzheimer's disease	n/a

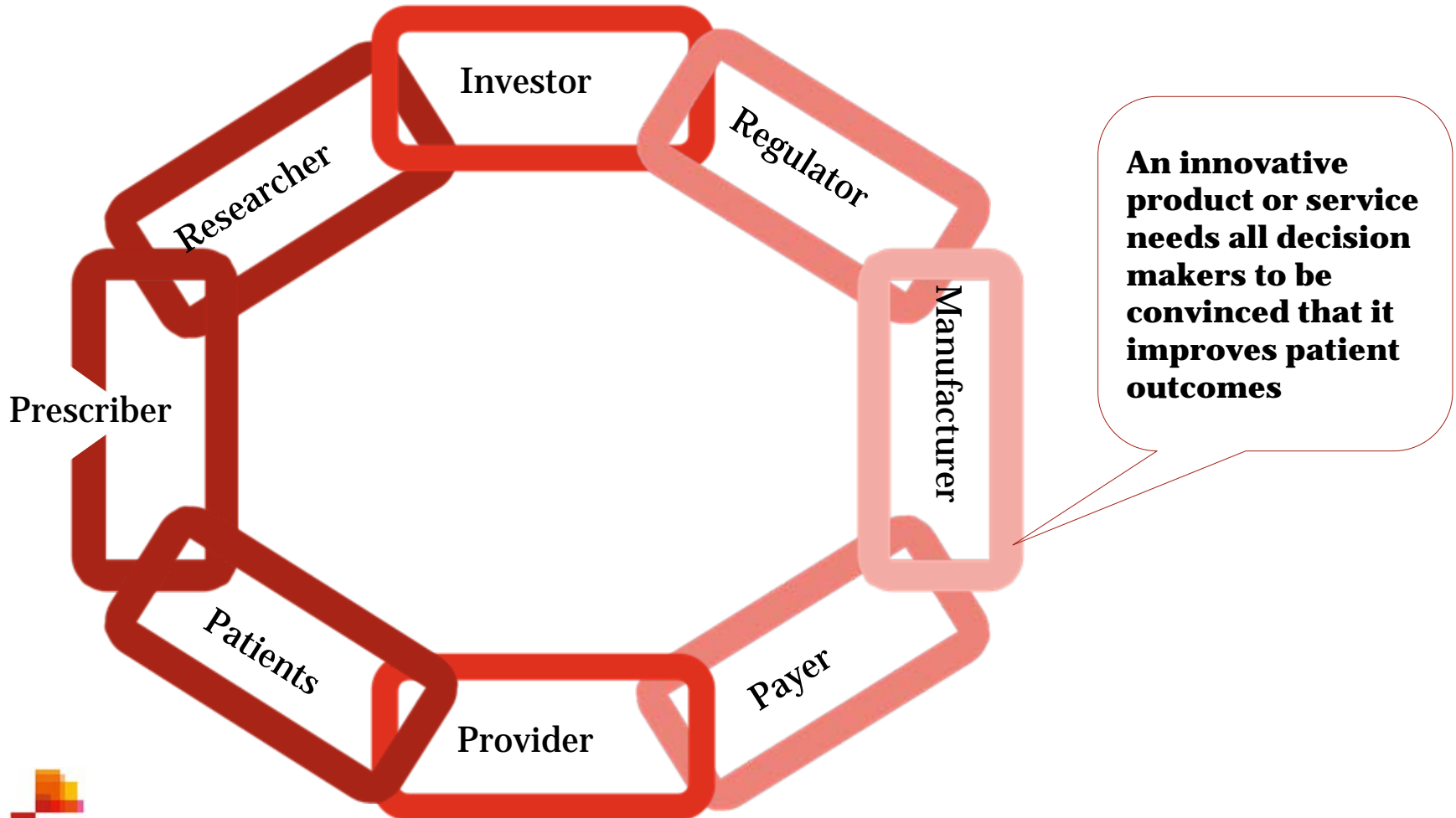
Failure to effectively manage the 25% of people that consume 75% of costs

What does Innovation mean to payers and providers?

$$\text{Innovation} = \frac{\uparrow \text{Quality} \times \uparrow \text{Service}}{\downarrow \text{Time} \times \downarrow \text{Cost}} = \text{Value}$$

Pharma needs to reduce the risk that products in R&D will meet the markets expectation for Value: **De-Risking**

Innovation is a team sport: All stakeholders must be convinced the products and services are innovative



Companies are using innovations in novel ways to create new business model for “owning the disease”

Companies

sanofi

GE Healthcare



Lilly

Lilly

MCKESSON

Empowering Healthcare



NOVARTIS

AgaMatrix



SYNTHES



Medtronic

US Oncology

AMS
Solutions for Life

GEN-PROBE

Owning

Diabetes

Diagnostics and Cancer

Orthopedics and osteoporosis

Parkinson's Disease

Cancer

Urology

STDs

Technology is Changing the Game

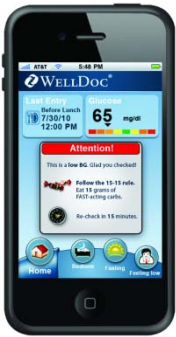
- Patients are becoming better informed and more aware of alternative treatments and outcomes data
- Methods of remote patient monitoring are becoming more prevalent and sophisticated
- Life Sciences sector is increasingly partnering with tech companies and providers
- The complexity of customer channels is increasing, driving supply chain transformation



- A powerful device
- On the person
- Always networked
- Always on
- Now what?

Innovation and experimentation - Telecos

WellDoc Chronic Disease Solution



- WellDoc solution automatically sends readings to cell phone app, which provides coaching and sends information to EMR and care providers
- Telco hosts, markets, and sells the solution; plans to pilot Diabetes Manager with Telco and HCSC employees
- Considered a potential “watershed moment” by industry press

Vitality GlowCap



- GlowCap replaces the lid on standard prescription pill bottles. Telco provides the wireless service enabling the device
- Functionality: personal reminders, pharmacy coordination, adherence reporting to physicians and family members

Lifesource Wireless Monitoring System



- Home wireless wellness system, including activity monitor, blood pressure monitor and scale
- Daily tracking and monitoring encourages individuals' awareness of own health
- Data transmitted to online service for display and remote access

MobileHelp



- MobileHelp launches patient-controlled emergency monitoring device using Telco's mobile network to communicate when a patient is away from their home station.

New healthcare & wellness ecosystem is emerging

Health literacy

- RSS, podcasts, search tools
- Stay informed of latest developments
- Used by medical professionals and public

Medical education

- Professional development for doctors
- Public health promotion by professionals and the general public

Collaboration & practice

- Tools for doctors and nurses to find information and make decisions in daily practice
- Product development and innovation

Manage disease/ promote wellness

- Search tools for patients
- Find information about particular condition

Share data

- Patient-reported outcomes
- Data aggregated for personal and scientific research

