Sticker Shock!

CHSPR 27th Annual Health Policy Conference

Establishing & Assessing Prescription Drug Prices

Valorem est in oculis aspicientis

W. Neil Palmer

Vancouver March 2015

Outline

- How do manufacturers set prices?
- How are prices assessed by regulators / payers?
- Outlook for pharmaceutical pricing

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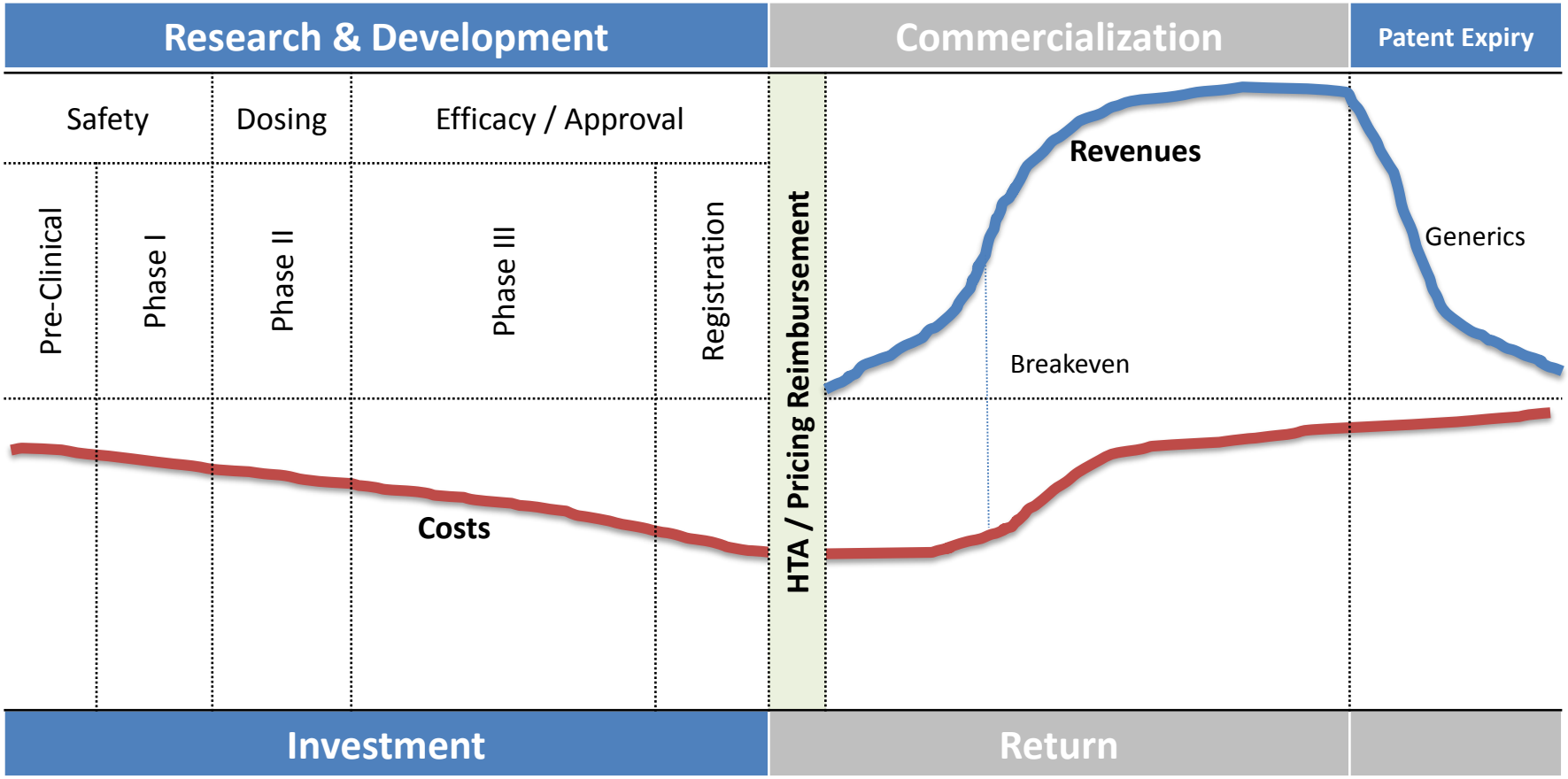
Factors in setting pharmaceutical prices

- Return on investment
- Competition / Market forces
  - Prices of alternatives
- Price regulation / HTA / reimbursement policies
- International /global
  - External price referencing
  - Potential for parallel trade
  - Differential / tiered pricing

Pharmaceutical Product Lifecycle



Adapted from valuationlab.com

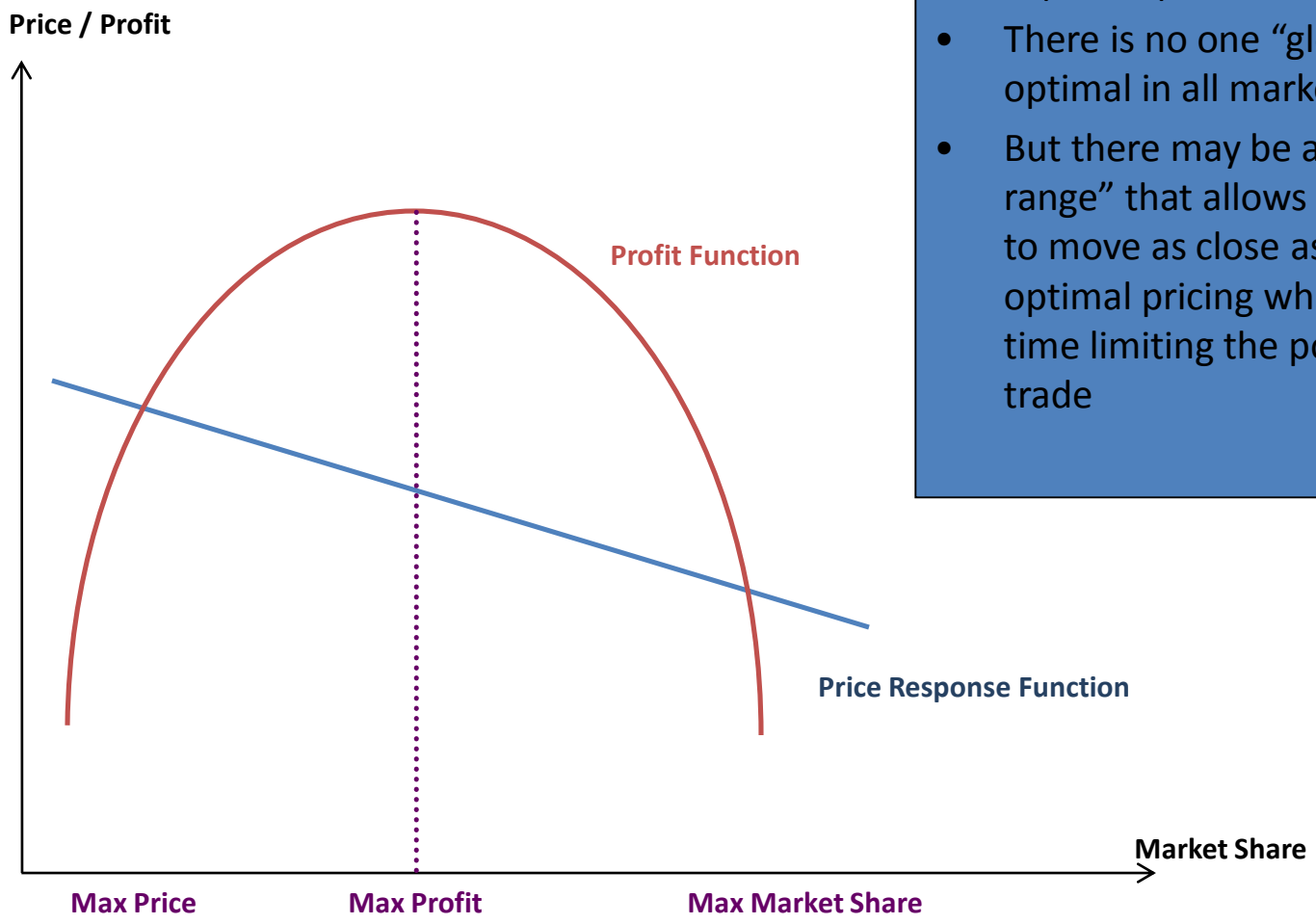
P&R Activities over Product Life Cycle

Pre-clinical	Phase I	Phase II	Phase III	Filing / Pre-marketing	Launch / Contracting	Post Launch Price Mgmt
Market assessment	Identify comparators	Finalize global pricing strategy	Negotiate prices	Price change approval
Pricing environment	Define outcomes, trial endpoints	Define price corridor / fix target and floor prices for each market	Negotiate risk-sharing / price-volume agreements	Report / assess mandatory price changes
NPV calculations	HE study design	Define launch sequence	Launch approval	Monitor price trends globally
Business planning	Identify P&R barriers	Develop global value / P&R dossier	Monitor launch process	Assess impact of exchange rates
Initial pricing scenarios	Monitor competitors	Develop market specific dossiers for affiliates	Indication sequencing	Assess impact of new indications
Market potential based on price scenarios	Quantitative research			
Early engagement meetings with payers / HTA agencies	Payer research			
	Analysis of value scenarios			
	Initial pricing strategy			

Adapted from Simon - Kucher

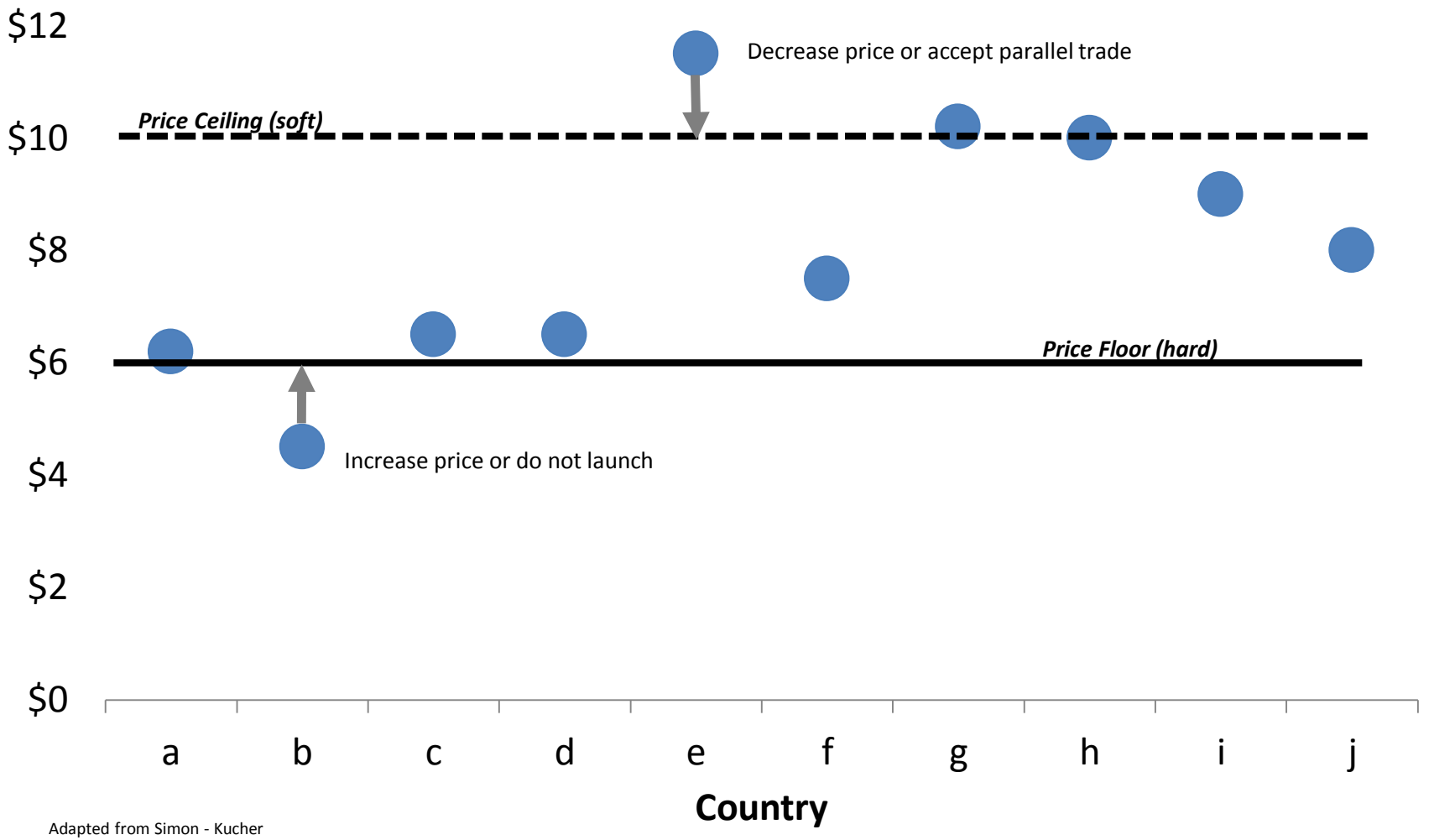
- P&R assessments and planning begin early in the clinical development process
- Important that there is collaboration and buy-in among clinical, HE/OR, P&R, affiliates

Market Pricing….



- Each Market has its own unique "optimal price"
- There is no one "global" price that is optimal in all markets
- But there may be an optimal "price range" that allows individual markets to move as close as possible to optimal pricing while at the same time limiting the potential for parallel trade

International Pricing Corridors



Adapted from Simon - Kucher

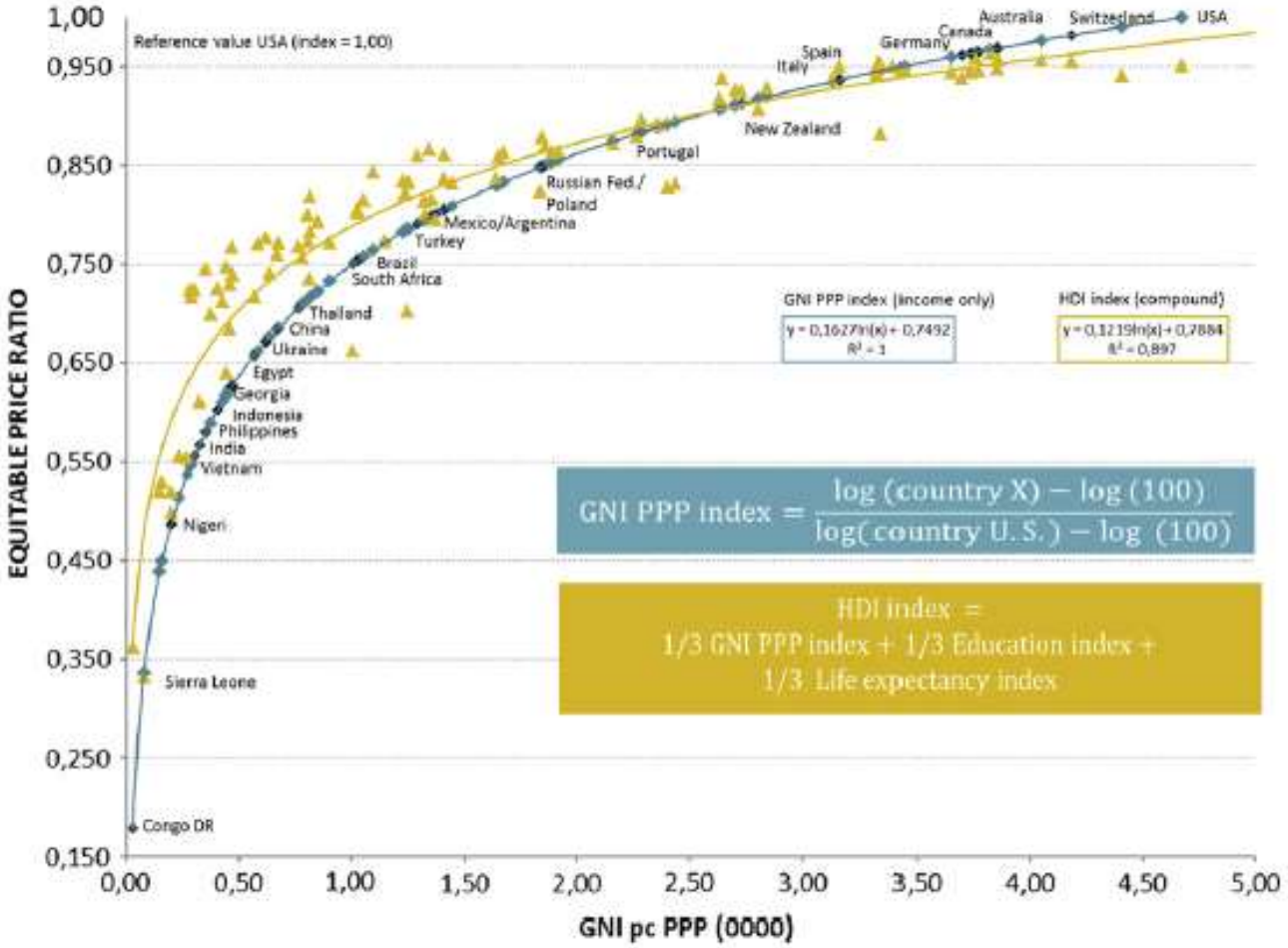
Tiered / Differential Pricing

- Rooted in “Ramsey pricing theory”
- To maximize social welfare monopolist price premium should be inverse of demand elasticity
  - Low prices for low-income markets with high demand elasticity
  - High prices (designed to recover R&D costs) for high-income markets with lower demand elasticity
- Some pharmaceutical manufacturers have established tiered (differential) pricing
  - Developed, emerging, 3rd world markets
- UN based Medicines Patent Pool facilitates low cost generic HIV medicines in 3rd world countries

Frank P. Ramsey

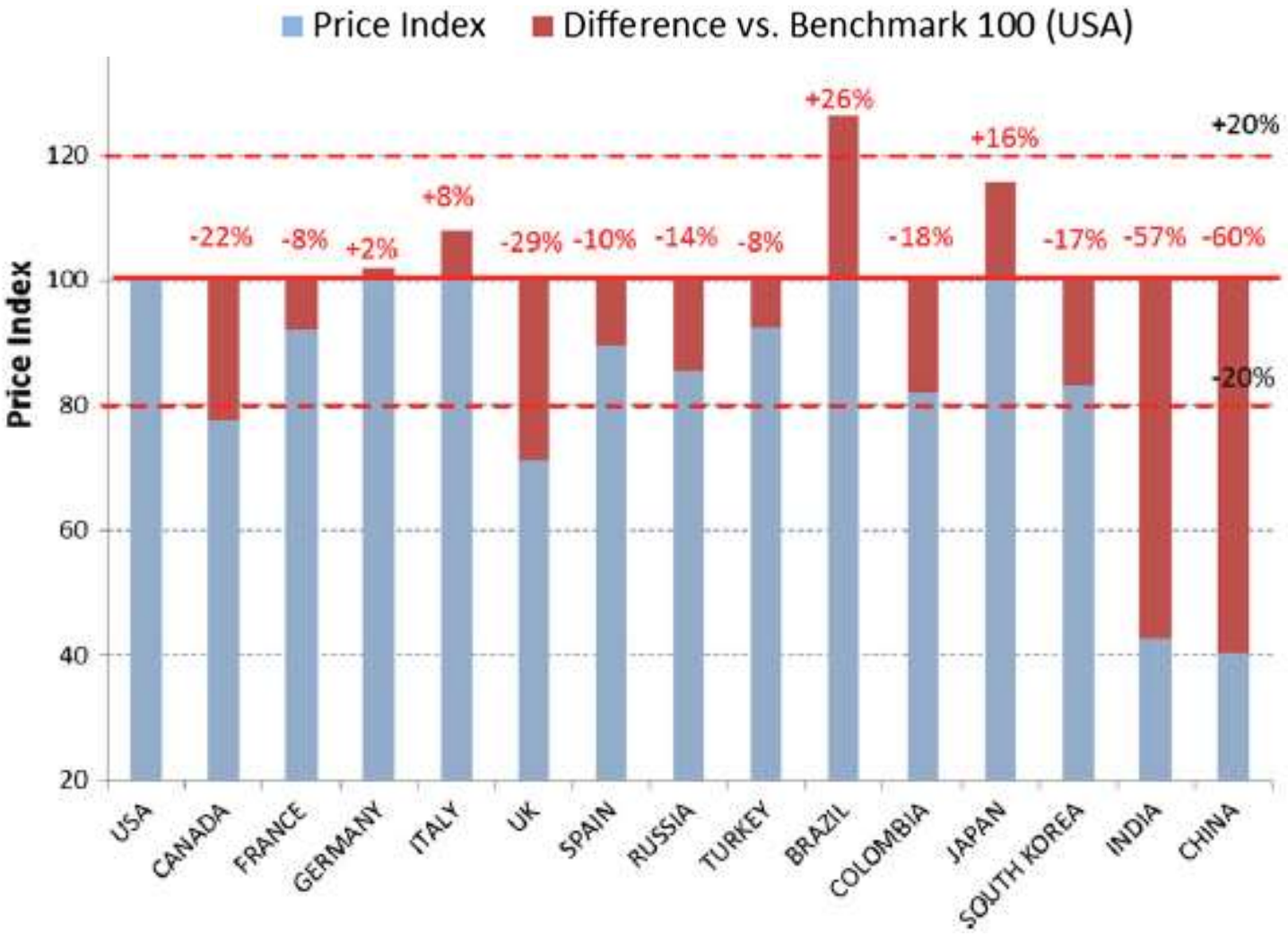
medicines patent pool

Pricing using HDI and GNI-based indexes.



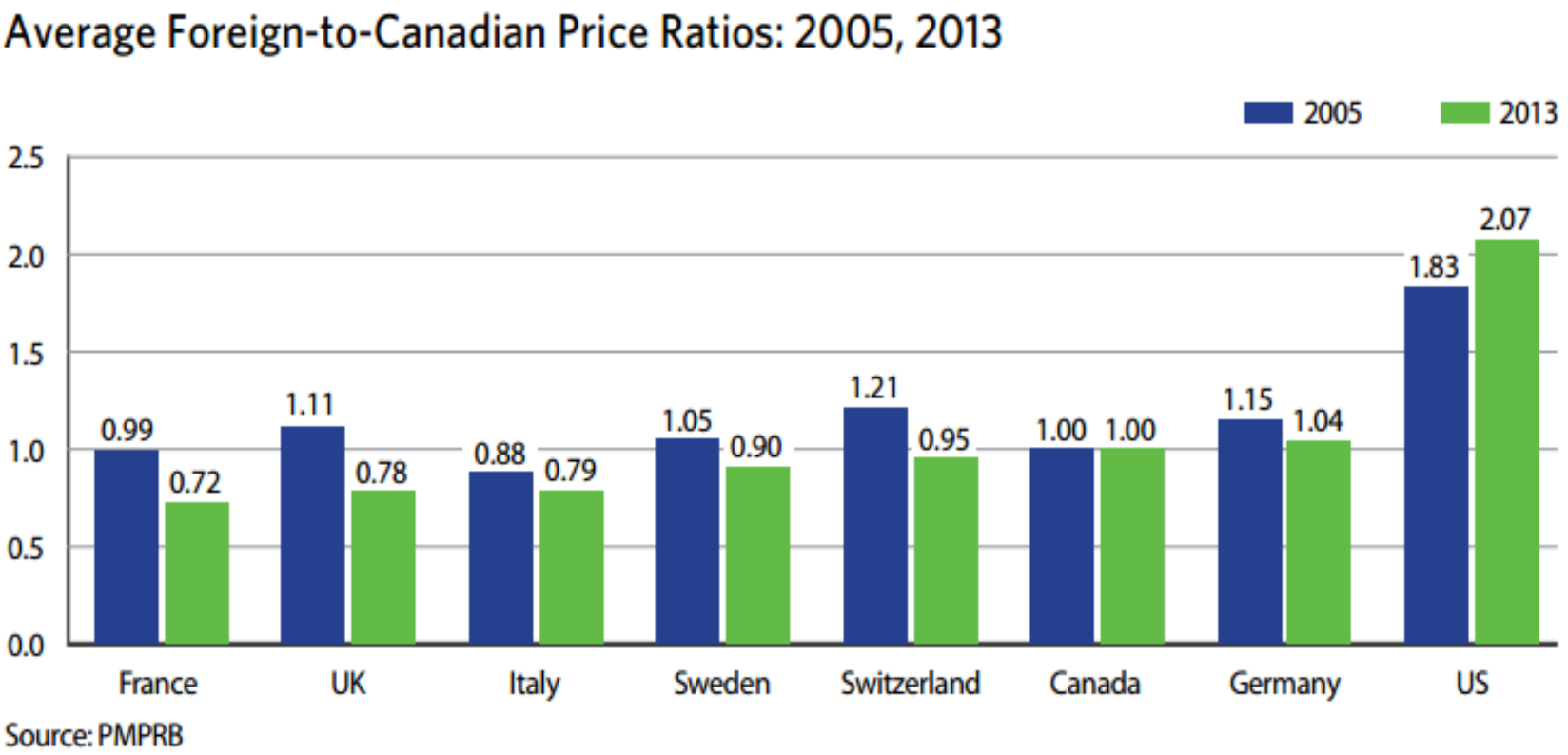
Source:: Daems, Maes, Glaetzer, et al

Ability to Pay - Gap Analysis (2010)



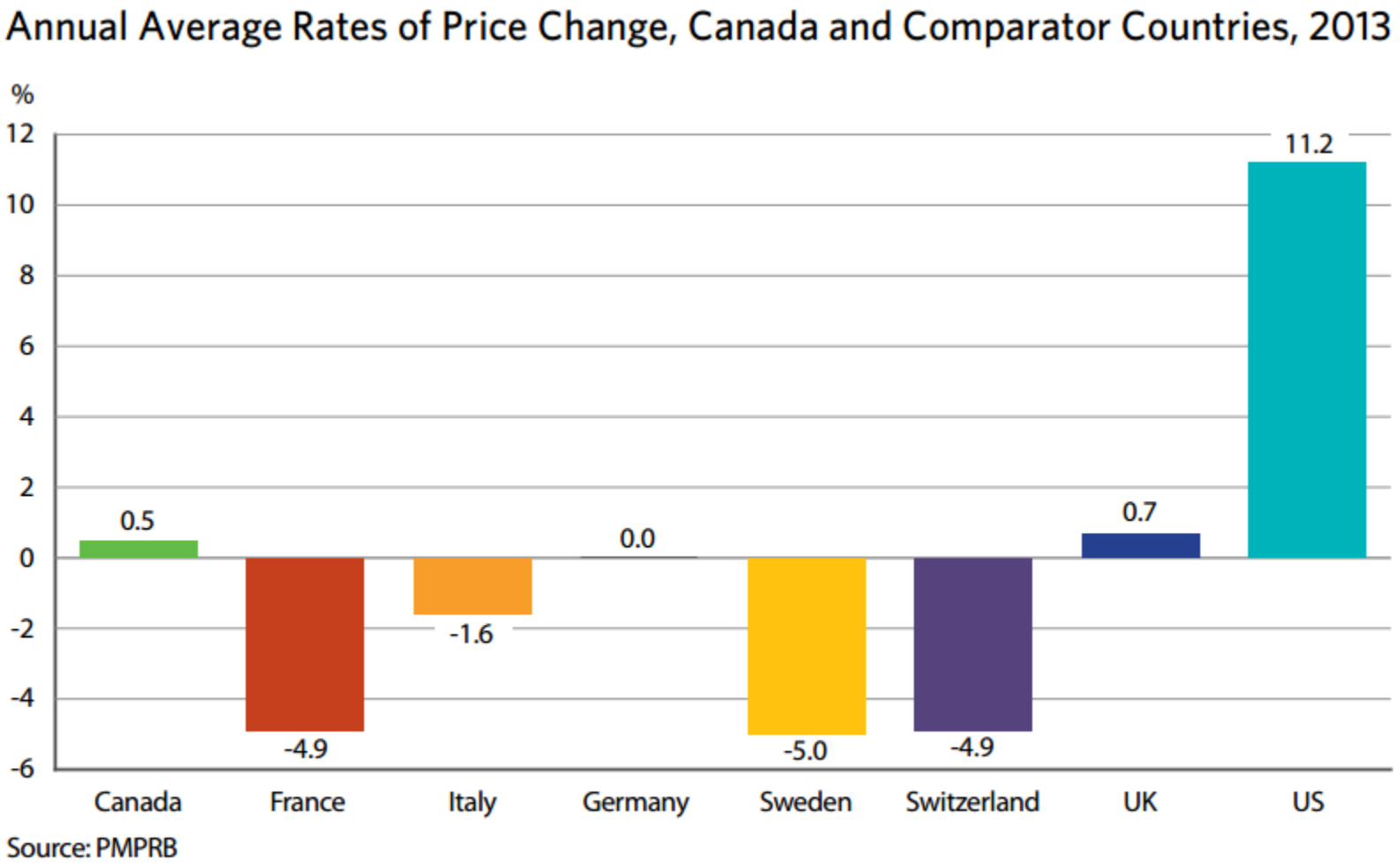
Source:: Daems, Maes, Glaetzer, et al

Canada vs. International Price Trends (PMPRB)



- Canadian prices higher than most European prices
- There may be changes in PMPRB price guidelines if “high” Canadian prices persist

Price Change – PMPRB Reference Countries



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Canada - PMPRB New Medicine Tests

Level of Therapeutic Improvement	Price Test	All Patented Medicines
Breakthrough	Median International Price	Prices of patented medicines can never exceed the International Maximum Price
Substantial Improvement	Higher of TCC & Intl. Median	
Moderate Improvement	Midpoint TCC & Intl Median (but not lower than TCC)	
Slight or No Improvement	TCC or Reasonable Relationship Test	

TCC = Therapeutic Class Comparison

Germany

The Federal Joint Committee in Germany (GBA) commissions IQWiG examines the benefits and harms of medical interventions and recommends level of additional benefit

Additional Benefit	Price Discount Negotiation	Implications for Pricing	European Prices Considered
Major Moderate Marginal	Yes	Adjusted premium vs. the appropriate therapy in pricing negotiation	Yes
Not Quantifiable	Yes	Similar to above	Yes
None	No (negotiation only if there is no reference group or comparator)	Reference price or at max. the price of the appropriate comparative therapy	No
Less Benefit	Yes	Discount vs. the appropriate comparative therapy	No

Adapted from: : Markus Jahn, Novartis Pharma GmbH, Pharma Pricing & Market Access Outlook, March 2012

France

Amélioration du service médical rendu (ASMR): *Clinical Improvement as a basis of price negotiation*

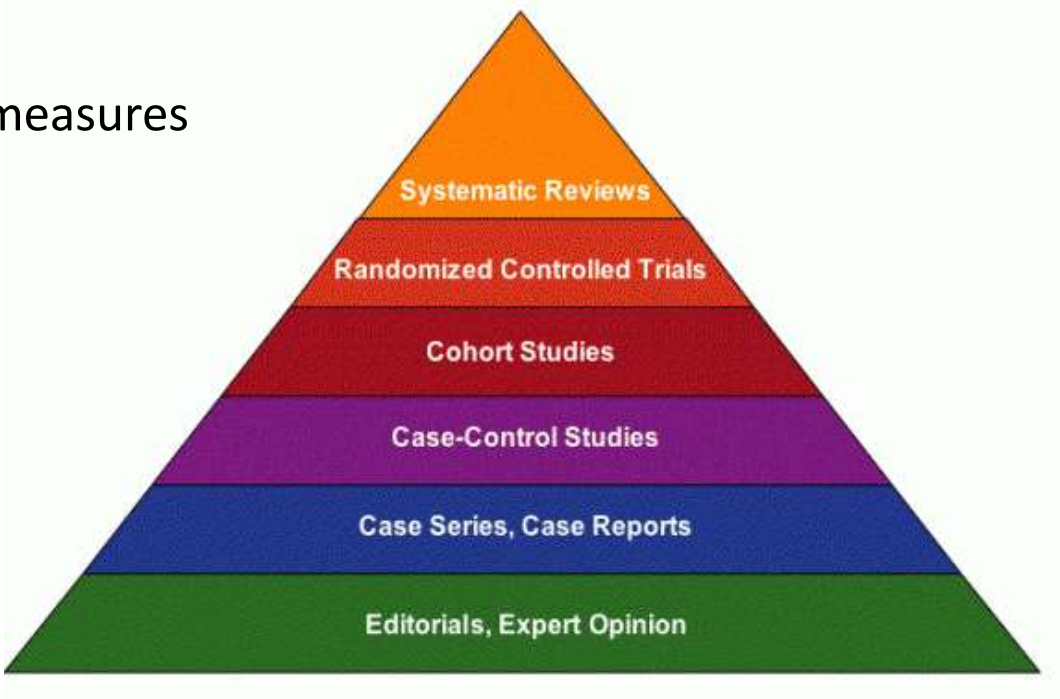
ASMR	Clinical Improvement		Price Implications
I	Major	innovative product of significant therapeutic benefit	Premium possible
II	Important	product of therapeutic benefit, in terms of efficacy and/or reduction in side effect profile	Premium possible
III	Moderate	moderate improvement in terms of efficacy and/or reduction in side effect profile	Premium possible
IV	Minor	minor improvement in terms of efficacy and/or utility	Price no higher than comparators
V	None	no improvement	Price must be lower than comparators
VI	Not Reimbursable		

Market Access Hurdles

Market Access Hurdles		Output
1. Safety 2. Efficacy 3. Quality	Required for Registration/ Market Authorization	Market Authorization
4. Value	Clinical Effectiveness, Cost Effectiveness	Reimbursement / Funding Recommendation
5. Price	Internal & External Price Referencing	Price Ceiling
6. Affordability	Budget Impact, Risk Sharing	Price / Volume, P4P Agreements
7. Local / Regional	Financing / funding	Local Guidelines Funding decision

Important HTA Factors

- Medical importance / Burden of illness / Unmet need
- Clinical (comparative) effectiveness thresholds
  - Additional Benefit (Germany)
  - Level of Improvement (Canada)
  - ASMR (France)
  - Italy, Japan have similar measures
- Cost Effectiveness
  - ICER (e.g., QALY)
  - Quality of Life
- Quality of Evidence
  - Double blind RCTs ?
  - Comparators



International Health Technology Assessment Agencies

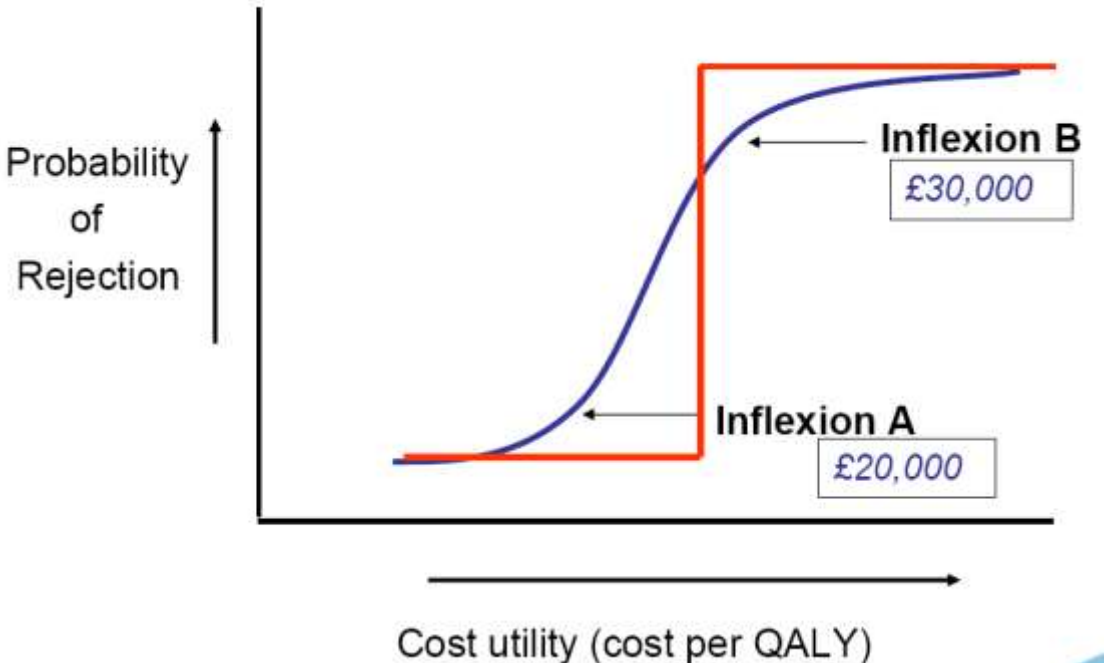
Country	HTA Agency	Responsibilities
United Kingdom	National Institute for Health Care & Excellence (NICE)	Clinical & Economic
Scotland	Scottish Medicines Consortium (SMC)	Clinical & Economic
Germany	Institute for Quality and Efficiency in Health Care (IQWiG) Federal Joint Committee (G-BA)	Clinical
France	Haute Autorité de Santé (HAS)	Clinical
Australia	Pharmaceutical Benefits Advisory Committee (PBAC)	Clinical & Economic
Canada	Canadian Association for Drugs and Technologies in Health (CADTH)	Clinical & Economic

Local & Regional Authorities affect Funding

- United Kingdom
  - England: 67 Clinical Commissioning Groups plus hospital trusts
- Spain
  - 17 autonomous regions + 2 autonomous cities
- Italy
  - 20 regions
- Germany
  - ~160 Sick funds
- Sweden:
  - 21 County Councils
- Canada
  - 10 provinces, 3 territories, federal plans, private payers
- United States
  - Medicare, 50 State Medicaid, hundreds of private insurers…

UK / NICE Cost effectiveness thresholds

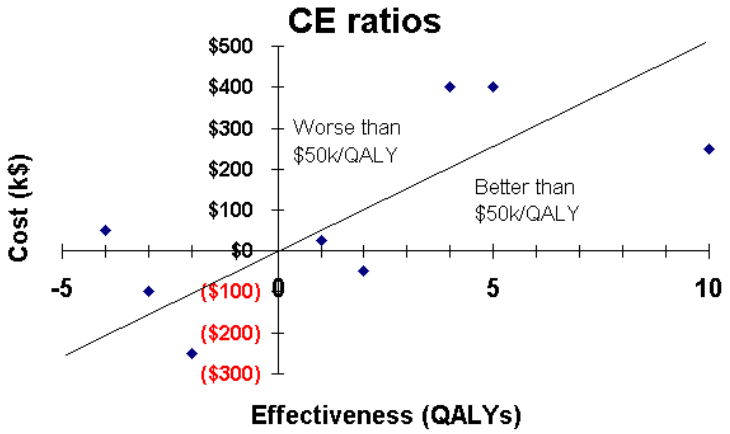
- Probability of rejection increases quickly above £20K/QALY
- NICE has issued supplementary guidance for life-extending, end-of-life treatments:
  - Life expectancy < 24 months
  - Life extension of at least 3 months
  - No alternative treatment
  - Small patient population
- For drugs that meet all criteria, NICE will consider:
  - Assigning greater weight to QALY benefits
  - Assessing the weight of QALY benefits needed to bring ICER within current threshold range (i.e., ≤ £30K/QALY)



Source: Longson C (NICE), *The NICE Health Technology Appraisal Programme (April 2008) / NICE: Appraising life-extending, end-of-life treatments, January 2009*

Health Economics: Advice to Manufacturers

- **Caveat: Health economics cannot save poor or irrelevant clinical data**
- Health economic considerations need to be incorporated into phase III clinical trial program
  - Trial design (head to head preferred)
  - Selection of relevant comparators
    - (gold standard preferred)
  - Relevant patient populations
  - Selection of relevant outcomes
  - Sub group analyses
  - Time horizon
  - Use of validated instruments to measure of quality of life (e.g., EQ-5D)



- Review HTA agency assessments of competitor products to understand strengths, weaknesses of their economic models
- Seek early engagement with HTA agencies for advice

Pricing & International Price Referencing

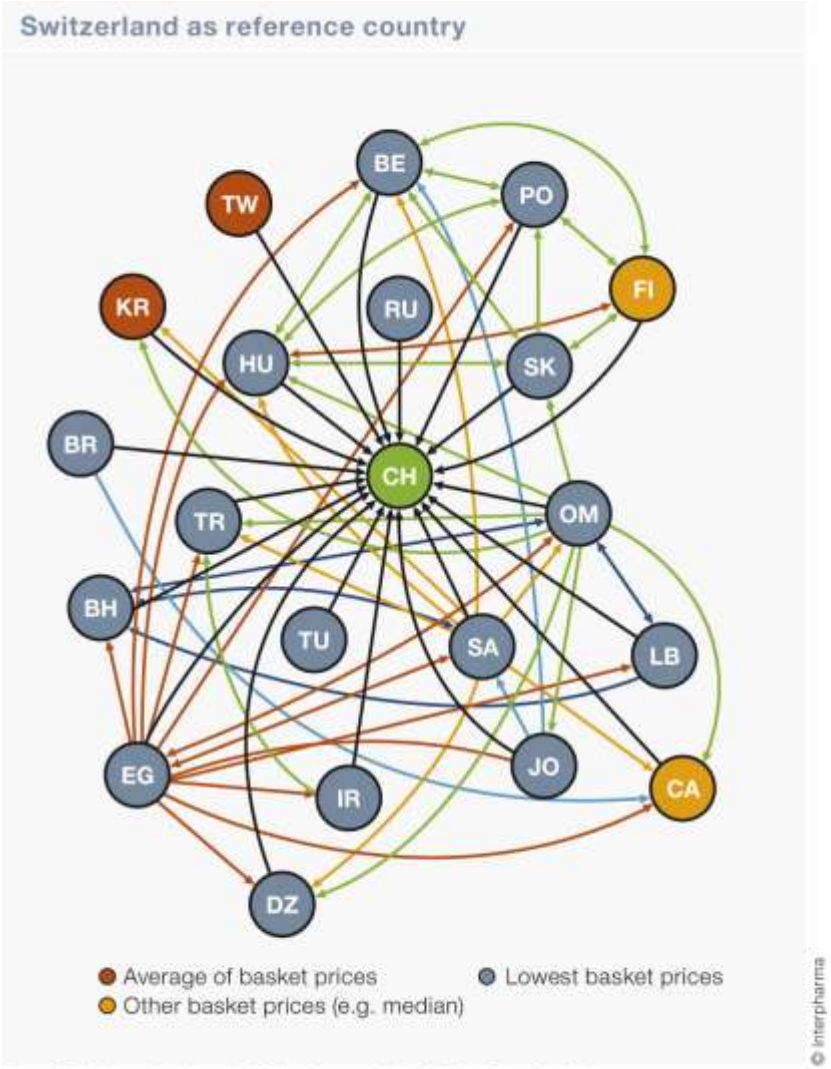
- A single global price is not feasible nor desirable.

- Even if prices are launched at the same global price:
  - Currency exchange fluctuations are beyond the control of manufacturer
  - Price cuts are common in many European markets
  - Price increases are possible in the US, and to a limited extent in Canada but rarely in Europe and Japan
  - Reimbursement status is reviewed periodically in some markets which can lead to new price negotiations
  - New national policies (e.g., Germany)

- Optimize launch prices in each market, take into account the effects of:
  - Local clinical practice
  - Country to country price referencing
  - Referencing to local product prices
  - Parallel trade
  - Future price cuts

External Price Referencing

- Most countries (other than the UK) apply some form of external referencing
- Approaches / methodologies vary significantly



Source: The international impact of Swiss drug regulation, Charles River Associates, study on behalf of Interpharma and Novartis, March 2013.

European External Price Referencing

Overview of country baskets in Europe (2013)

	AT	BE	BU	CH	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE	IS	IT	LT	LU	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	UK	Add. countries	N. of countries
AT		■																■	■	■	■	■	■		■	■		■	■	■	■		24
BE	■		■		■	■	■	■	■	■	■	■	■		■	■		■	■	■	■	■	■		■	■		■	■	■	■	Or Country of origin	26
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CH	■						■	■					■										■								■		6
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ES	■	■			■		■		■	■		■	■			■		■		■		■	■			■			■	■		Eurozone but not regulated	16
FI	■	■	■		■	■		■	■	■	■		■		■	■	■	■	■	■	■	■	■		■	■	■	■	■	■	■	Liechtenstein	29
FR							■				■							■													■		4
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HU	■	■	■	■	■	■	■	■	■	■	■	■	■	■		■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	Liechtenstein	31
IE	■	■					■	■				■	■										■								■		9
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IT	■	■	■		■	■	■	■	■	■	■	■	■	■	■	■			■	■	■	■	■		■	■	■	■	■	■	■		27
LT			■			■			■						■						■				■		■			■			8
LU																																Country of origin	1
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MT					■	■			■		■				■			■	■							■			■	■	■	Public sector*	11
NL		■					■						■																				4
NO	■	■					■	■				■				■							■					■			■		9
PL	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■		■	■	■	■	■	■	Liechtenstein	31
PT											■		■																		■		3
RO	■	■	■			■	■			■	■				■			■	■						■					■			12
SE																																	n/a
SI	■						■						■																				3
SK	■	■	■		■	■	■	■	■	■	■	■	■	■	■	■		■	■	■	■	■	■		■	■	■	■	■	■	■		27
UK																																	n/a
Reference frequency	16	15	9	2	10	13	17	15	12	13	16	15	19	5	13	13	3	15	14	9	11	8	15	6	10	13	10	13	13	16	17		

Source: European Commission, External reference pricing of medicinal products: Simulation-based considerationsfor cross-country co-ordination

*For private sector in Malta, data from 12 European reference countries, classified in a three-tier system, is used for ERP: Low- priced tier: ES; UK; PT; FR/Medium-priced tier: BE; IS; CY; IT/High-priced tier: DK; DE; IE; NO. AT, Austria; BE, Belgium; BG, Bulgaria; CH, Switzerland; CY, Cyprus; CZ, Czech Republic; DE, Germany; DK, Denmark; EE, Estonia; EL, Greece; ES, Spain; FI, Finland; FR, France; HR, Croatia; HU, Hungary; IE, Ireland; IS, Iceland; IT, Italy; LT, Lithuania; LU, Luxembourg; LV, Latvia; MT, Malta; NL, the Netherlands; NO, Norway; PL, Poland; PT, Portugal; RO, Romania; SE, Sweden; SI, Slovenia; SK, Slovakia; UK, United Kingdom

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New Challenges: Gene & Cell Therapy

- More complex / uncertain than traditional pharmaceuticals
  - Similarities with diagnostics and devices

- New cell & gene technologies may be assessed by traditional "national" HTA methods, but:
  - Payment / funding mechanisms may be local / regional
  - Procedure and fee codes may need to be established
  - Existing budgets may not be sufficient
  - Costs of ancillary care, treating adverse reactions

- Treatment pathways will vary across jurisdictions
  - Follow the treatment pathway to understand the payment / funding pathway

HTA of Cell & Regenerative Treatments

- Technological breakthrough ≠ Clinical breakthrough
- HTA agencies will apply traditional techniques to assess clinical , cost effectiveness
- Hepatitis C drugs (e.g., Sovaldi) have provided HTA agencies and payers with experience assessing "curative" technologies
  - 90 - 100% cure rates
  - Open, single arm trials
  - One time high cost treatment, but highly cost effective (low $/QALY)
  - Significant affordability issues (large untreated patient population)
- Payers in many markets have mechanisms for risk sharing agreements
  - Pay for Performance (P4P) – Outcomes based (e.g., Velcade UK)
  - Financial: price / volume agreements
  - Alternative approaches for high cost "curative" treatments?

Annuities as alternative payment mechanism

- **Objective** – to defer and spread cost over several years to address affordability / budgetary concerns
  - Technology cost would be reimbursed up front with the balance amortized over several years
- **Issues to consider:**
  - Infrastructure for tracking patients, managing payment system
  - Patient mobility: change in insurer / jurisdiction (who pays?)
  - Patient dies or has recurrence of disease / injury
  - Cost of treating side effects (who pays?)
  - Multiple payers, Patient co-pay
  - Better, lower cost therapies emerge (will payers want to continue payments for the high cost treatment)
- **Possible role for 3rd parties**
  - Financing
  - Monetizing future payments

International Changes that affect Market Access

- United States
  - Affordable Care Act (Obamacare)
- Germany
  - AMNOG (Arzneimittelmarktneuordnungsgesetz)
- United Kingdom
  - Value based pricing? Value based assessments? Price Cuts…
- Canada – Integration / harmonization of HTA
  - CDR + pCODR, Pan Canadian Pricing
- Other markets
  - Mandatory price cuts
  - Comparative effectiveness
- Greater transparency, collaboration by HTA agencies
  - Greater emphasis on assessing therapeutic improvement
- Early engagement with HTA and Regulators

Outlook Summary

- Continuing cuts in health (and drug) budgets
- Focus on “cost effectiveness” does not address affordability
- International price referencing pushing prices down
- “Therapeutic improvement” / “additional benefit” the basis for establishing prices and levels of reimbursement
- “Value based pricing” not practical
- Risk sharing schemes (listing agreements) a stop gap measure to address clinical uncertainty, international price referencing
- HTA agency collaboration to harmonize definitions but not decisions
- Ethical, societal perspectives, patient involvement to expand
- Drug costs continue to be the “low hanging fruit”

Thank you

Biography

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- **Neil Palmer** is President and Principal Consultant of PDCI Market Access Inc (PDCI) a leading pricing and reimbursement consultancy founded as Palmer D'Angelo Consulting Inc (PDCI) in 1996. He leads a senior team of market access professionals with pricing & reimbursement engagements covering Canada, Europe, and the United States. In December 2006, PDCI became a subsidiary of RTI Health Solutions of RTP North Carolina where Neil served as global vice president before re-acquiring the company in 2009. Prior to PDCI, Neil worked with the Canadian Patented Medicine Prices Review Board (PMPRB) where his responsibilities included policy development, overseeing the price review of patented medicines and conducting economic research. He is a frequent speaker at pharmaceutical conferences in North America and Europe

- **PDCI Market Access (PDCI)** is a leading Canadian market access consultancy featuring an experienced pricing and reimbursement team with long-established relationships with the Patented Medicine Prices Review Board (PMPRB), the Common Drug Review (CDR), federal/provincial/territorial (F/P/T) drug plans, the pan Canadian Oncology Drug Review (pCODR), and major private payers. Our goal is to assist clients in establishing and maintaining optimal prices while maximizing market access in both the public and private sectors. PDCI's consulting services are supported by the C-MAP™ Solutions series including the highly respected Canadian Drug Benefit Plans (CDBP) Reference Guide, an industry standard for more than 10 years, and the C-MAP™ Canadian Drug Claims Database. PDCI has a staff of twenty-two including senior consultants with expertise in strategic planning, pricing, market access, and reimbursement for the pharmaceutical, biotechnology, and medical device sectors.