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## Value-Based Pricing in Developed and Emerging Markets- Past, Present and The Future

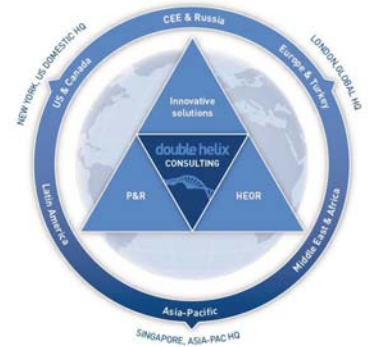
November 5<sup>th</sup> 2011  
14<sup>th</sup> European ISPOR Congress  
Madrid, Spain



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### Aim of this symposium

- To understand how value based pricing is perceived by different stakeholders
- To discuss the trends in VBP in the developed and emerging markets
- To assess the challenges in implementing value based pricing system; from both budget holder as well as industry perspective



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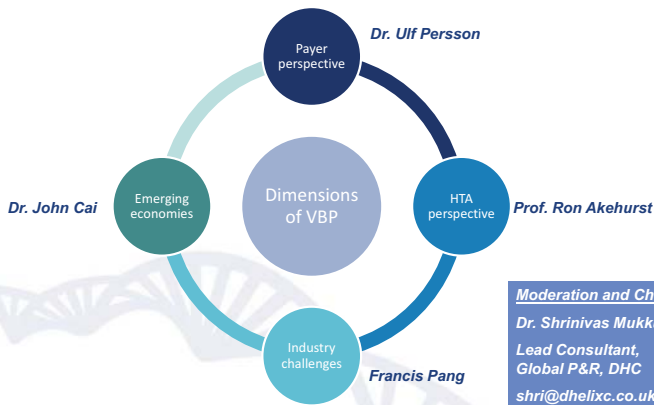
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### Our distinguished speakers



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## Value Based Pricing (VBP) of pharmaceuticals: Development of VBP in Europe over the years

Ulf Persson

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&

Institute of Economic Research, School of Economics and Management, Lund  
University, Sweden

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Value Based Pricing, ISPOR, Madrid 2011

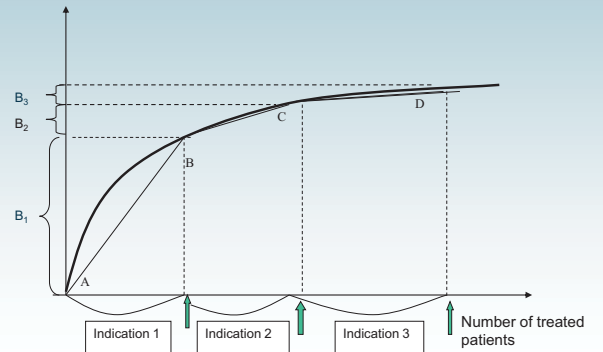


## Value based pricing (VBP)

- Value Based Pricing
  - Price based on perceived value to customer
- Cost-plus pricing
  - Cost of producing product or service and adds an amount needed to make a (minimum) profit

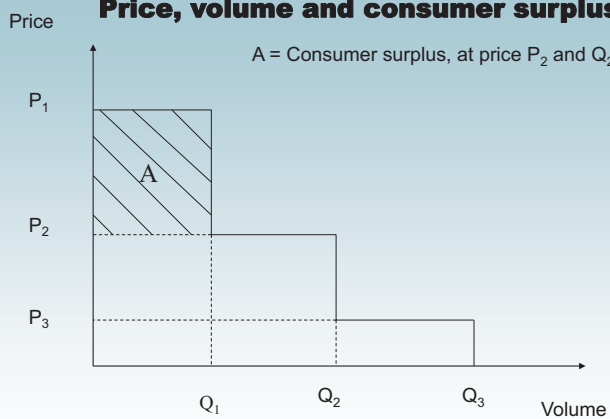
## Diminishing marginal utility of drug treatment

Benefit of health:



## Value Based Pricing (VBP)

### Price, volume and consumer surplus

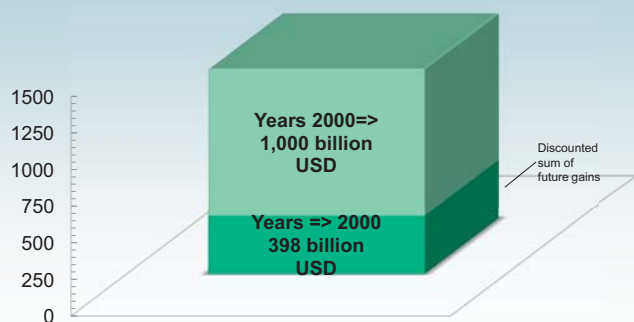


## How to define value in VBP ?

- No universal standard
- In pharmaceuticals: Often health economic evaluations
  - E.g. cost-effectiveness
- Decisions based on multi-criteria analysis
  - Sweden, three criteria:
    - Equity
    - Severity of the disease
    - Cost-effectiveness

## What is the Value of innovative medicines?

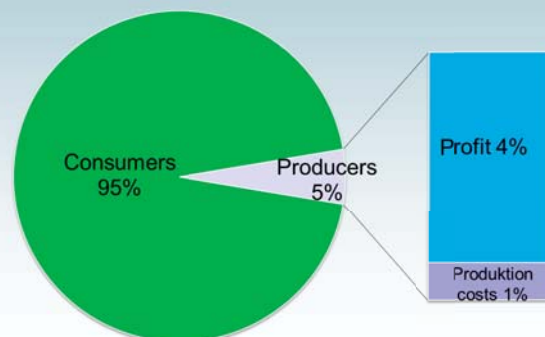
**An example:**  
**Value of HIV/AIDS medicines (billion USD)**  
 Estimated by Philipson & Jena, 2005 assuming the value of a life-year equals to \$100,000



Value Based Pricing, ISPOR, Madrid 2011



## Value of HIV medicines (1,400 billion USD) Distribution between consumers and producers



Value Based Pricing, ISPOR, Madrid 2011



## Conclusions from medical treatments of HIV/AIDS Philipson & Jena, 2005

- Consumers/patients receives most of the value of innovative medicines (95%)
- Manufacturers/innovators receives 5%
- Important that the value of pharmaceuticals are estimated over the entire life cycle of the drugs

Value Based Pricing, ISPOR, Madrid 2011



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## VBP Costs per QALY gained

QALY= Quality Adjusted Life Year

### Incremental Cost-Effectiveness Ratio (ICER):

$$\frac{\text{Costs treatment A} - \text{Costs treatment B}}{\text{QALY treatment A} - \text{QALY treatment B}}$$

**Price can be justified if ICER is below, e.g.:**

**Limited budget perspective, the UK: £30,000**  
**Broad societal perspective, Sweden: €90,000**

Value Based Pricing, ISPOR, Madrid 2011



## Swedish experiences of VBP

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**System has worked reasonably well  
Price premium for innovations was awarded**

### Some examples from diabetes (insulin)

- NPH insulin € 1.50 per day
- Insulin analogs (Lantus, Levemir) € 1.90 per day:
  - Similar HbA1c, but less weight gain and lower risk for hypoglycemia
- GLP-1 analog (Byetta) € 3.20 per day
  - Similar HbA1c, but reduce weight and postpone diabetes progression

**Intrinsic problem or contradiction in the Swedish system:**

**National reimbursement decision (Value) but regional health care system (Cost containment)**

- Decisions on use (quantities) are taken at regional level
- Regions/health care providers focus on budgets (price times quantities)
- Consequence: Regional variations in the use of new innovations; over or under (most common) the indications for which Value was established

## "Post-code" prescription of TNF inhibitors for Rheumatoid arthritis in Sweden

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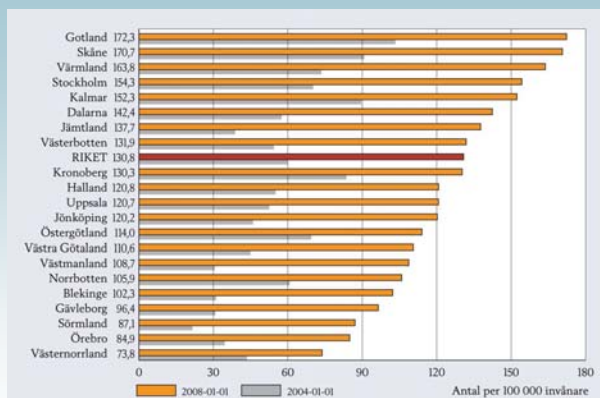


Diagram A-13 Antal patienter med biologiska läkemedel vid reumatoid artrit per 100 000 invånare, 2008-01-01.

Källa: Svenska Reumatologiska kvalitetsregistret

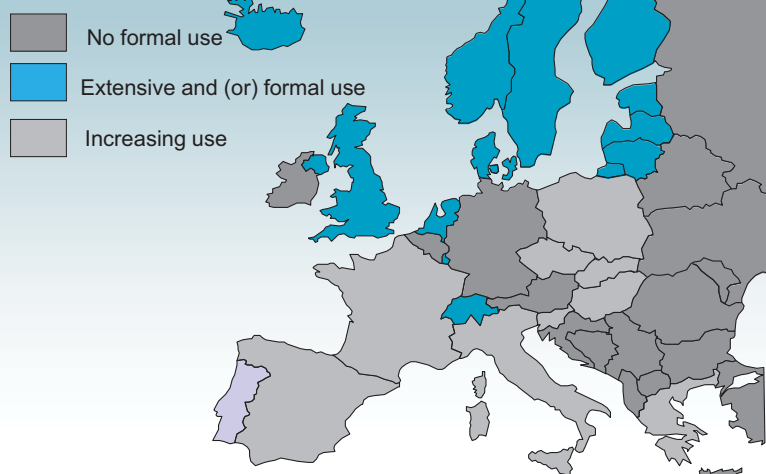
## Do Health Politicians Really Listen to Health Economists? Observations from Europe

Thomas Mittendorf et al  
16 November/December 2009 ISPOR CONNECTIONS

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- The UK
  - Health care reforms of the late 1980s –internal market into the UK NHS
  - NICE 1999, SMC
- Germany
  - "Slowly tries to catch up" and the new IQWiG..
- Sweden
  - LFN (now TLV), VBP of Pharmaceuticals since 2002
- Spain
  - Technology assessment units in some regions
- The Netherlands
  - Cost-effectiveness and budgetary impact dat of new drugs for reimbursement since 2005

## Where is VBP practiced in Europe?



## Discussion How does VBP work in reality?

1. Costs increase rapidly?
2. "Too high" prices, because WTP for health gain is known?
3. A sustainable system – access to new treatments and encouraging the development of innovations?

## Discussion VBP

The "Swedish" example for pharmaceuticals does not support the arguments that VBP should:

- -Increase costs more rapidly for pharmaceuticals than for other health care costs
- -Higher prices on pharmaceuticals when the society's willingness-to-pay is known
- However, VBP may make it difficult to receive reimbursement for orphan drugs
- "Post code prescriptions" on local levels where cost-containment is the dominant strategy

## Discussion Pros & Cons of VBP

- Cost-Effective use of health care resources
- Cost containment instruments
- A sustainable system – access to new treatments and encouraging the developments of new treatments
- Requires HTA to implement innovations
- Requires budget allocation of resources from not cost-effective to cost-effective technologies
- Difficult to justify orphan drug prices

## Value Based Pricing in the UK: How will it work and what might be its implications?

Professor Ron Akehurst  
School of Health and Related Research

## Content

- In this brief talk I intend to cover the current arrangements for drug pricing in the UK, what is proposed and what its implications might be.
- I must stress that much of what I say is not firm but is informed speculation on my part
- Most of the major issues are not yet resolved

## Drug Pricing in the UK

- There is currently no formal mechanism for the NHS centrally to negotiate drug prices but payers, such as Primary Care Trusts might directly negotiate discounts to list prices
- Manufacturers can set what price they wish for new drugs but their operation in the UK is subject to an upper limit on their total profits. They may only increase prices if profits fall below a lower limit and with permission from the DoH, under a scheme known as the Pharmaceutical Price Regulation Scheme (PPRS)

## NICE Approval

- Most new drugs (as well as many other technologies) are reviewed by NICE around the time they are launched in the UK for their clinical and cost effectiveness
- NICE has to advise whether drugs should be used in the NHS, given their price; in which patients and in what circumstances (e.g. only after failures of other, specified treatments and only until defined signs appear)
- Decision is therefore Yes/No and in whom
- Recently companies have negotiated Patient Access Schemes which have had the effect of lowering price as a means of getting a favourable decision

## The “Base Case”

- Currently, NICE appraisals centre around an economic assessment which produces estimates of the cost effectiveness of the drug in terms of cost/QALY together with associated uncertainty
- A strict NHS perspective is taken for the numerator and only effects on health related quality of life are included in the denominator
- Other costs and benefits may be taken into account in a decision but they are not included in the ratio

## The “Threshold”

- Currently, if the cost effectiveness ratio is below £20k per QALY compared to the agreed comparator(s) and the case is robust without too much uncertainty, the drug will be recommended
- This £20k has been assumed to represent the opportunity cost of resources used in health, on average.
- Above £20k other considerations, named but not quantified, come into play and above £30k the further considerations have to be particularly strong

## Arrangements from January 2014

- From 2014 the current PPRS will be scrapped and a new price negotiation machinery introduced
- A Value Based Price will be negotiated between the Department of Health and the manufacturer, reflecting the value of the medicine to the population
- NICE will play a major role in the analysis that will inform the decision of the DoH on the value of the drug

## New Weightings

Under the proposed arrangements the Government has stated that:

- i. there would be a basic threshold, reflecting the benefits displaced elsewhere in the NHS when funds are allocated to new medicines;
- ii. there would be higher thresholds for medicines that tackle diseases where there is greater “burden of illness”: the more the medicine is focused on diseases with unmet need or which are particularly severe, the higher the threshold;
- iii. there would be higher thresholds for medicines that can demonstrate greater therapeutic innovation and improvements compared with other products;
- iv. there would be higher thresholds for medicines that can demonstrate wider societal benefit

## A new basic threshold

- “The basic threshold need not be the one currently used by NICE. In developing value-based pricing, there would be a re-evaluation of the “basic” cost-effectiveness threshold, to put estimates of the value of alternative uses of NHS funds on a sound, evidence-based footing. This should ensure that the threshold is fit for purpose in the new system. Work is already in hand with external experts to achieve this.”

## Burden of Illness

- Under value-based pricing, there would be higher thresholds for diseases with higher “Burden of Illness”. The most important factors contributing to the measurement of “Burden of Illness” would be the severity of the condition and the level of unmet need.
- Severity is intended to reflect the health status without the new treatment, and also if the condition leads to premature death or serious morbidity.
- Unmet need reflects the degree to which there are existing treatments and clearly relates to the statement above.
- Conditions that are already well served with effective treatments would be scored at a lower level on this measure – even if the untreated condition was itself severe and life-threatening
- Work is currently under way to try to assess this weighting

## Therapeutic Innovation and Improvement

- Under value-based pricing, higher thresholds or maximum prices would reflect the scale of the “Therapeutic Innovation and Improvement” achieved by individual products. Therapeutic innovation and improvement would be assessed by whether a new medicine represented a significant improvement relative to existing treatments. It would reflect any additional health gain not captured by the normal pharmaco-economic assessment of the health gain because of measurement difficulties
- Not clear whether or how this will be included

## Wider Societal Benefit and economic evaluation

- The pharmaco-economic evaluation would be similar to the technology appraisal process currently carried out by NICE. It would calculate the patient health benefits of the product and reflect all costs and benefits beyond the direct purchase price of the medicine – including, for instance, cost savings elsewhere in the treatment pathway.
- However, it is intended that a wider range of benefits may be counted in the base case. Carer costs; carer losses in quality of life; crime reduction and employment benefits have all been mentioned
- The signs are that only carer costs and benefits will be included.

## Process: Steps proposed by NICE

- A “value dossier” from the company as in the STA process according to a NICE template, setting out both clinical effectiveness and cost effectiveness of the drug
- Expert panels to assess burden of illness and therapeutic innovation
- A New Medicines Panel which will incorporate the output from the expert panels and undertake a technical review of the value dossier
- An Appraisal Committee, which will consider the Burden of Illness, innovation and social value weights as they apply to a particular drug; prepare a statement of the optimal use of the drug in clinical practice and expose the outcome to consultation
- Once consultation was complete, this statement would be published

## Pricing negotiations

- NICE assumes that the output from their process would go to a pricing committee of the Department of Health for a price to be agreed
- NICE might continue to provide analytical support during the negotiations
- Once the price is agreed it is intended that the price/population package will be mandatory on Commissioners of health care

## Implications Elsewhere

- It is probably reasonable to assume that NICE reports will be as influential in other markets as they are now, that is , important in some but not others
- The UK is referenced for price by about 25% of the world’s pharmaceutical market, so the price set may matter

## Thank You for your Attention



# Mandatory Guidance

- As a consequence of the Sheldon et al research, NICE guidance was made mandatory
- The Government has recently declared that this mandatory component will be retained when VBP is introduced from 2014

## Value based pricing: an industry perspective

- Francis Pang
- Senior Director Market Access and Public Affairs
- Shire Human Genetic Therapies



## Background

- UK pharmaceutical industry delivers significant value to patients, the NHS and the UK economy
- Contribution greater than any industry sector generating trade surplus of more than £7bn
- PPRS has provided a stable and predictable environment for regulation of branded medicines
- Success means UK patients benefit from earlier and more consistent access to medicines
- UK accounts for 3% of worldwide sales for prescription medicines



## What are we moving from

### Key positive features of PPRS

- **Access**
  - ⇒ Freedom of pricing at launch
  - ⇒ Flexibility for pricing linked to new indications or new evidence
  - ⇒ More systematic use of patient access schemes
- **Promotion of innovation**
  - ⇒ R&D allowances designed to reward innovation
- **Low bureaucracy**
  - ⇒ Low touch and staffing costs for DH and industry
- **Conceptual appeal**
  - ⇒ Balance between R&D investment and innovation and secure reasonable prices for NHS
  - ⇒ Voluntary scheme
- **Stability**
  - ⇒ 5 year-term creates certainty for business planning
- **Flexibility**
  - ⇒ Modulation allows market responsiveness



## Andrew Lansley Mansion House Speech, Sept 29th 2009

- 'Our current understanding is that a new agreement will be negotiated with the DH to operate from 2014, which may include many current aspects of PPRS, given that value-based reimbursement will be probably be *prospective only*. Evolution to value based reimbursement will be gradual – probably no more than 20 new products each year and will build on patient access schemes and flexible pricing already introduced in the 2009 PPRS.'



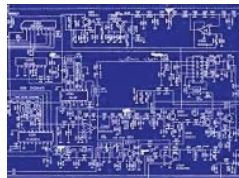
## Key strategic issues for VBP

- **Connecting value to access and uptake**
  - ⇒ Decisions on access to medicines are currently a devolved responsibility
  - ⇒ No secondary regional/ local blocks
- **Coherent UK pricing and reimbursement environment**
  - ⇒ Co-existence of value-based reimbursement for medicines launched after 1<sup>st</sup> January 2014 and voluntary agreement for existing marketed medicines 'successor scheme'
  - ⇒ Retention of freedom of pricing setting. VBP determines a 'reimbursement price'
- **Reimbursement pricing mechanism**
  - ⇒ Reimbursement negotiation process once value assessment completed
- **Fair reward for R&D investment**
  - ⇒ Recognition of types of innovation (incremental versus breakthrough)
- **Cost-effectiveness thresholds and weightings**
  - ⇒ Determination of thresholds and range of weightings based on severity/ burden of disease
- **Uncertainty in evidence**
  - ⇒ Evidence uncertainty should be reflected in VBP
- **Inclusion of devolved nations**
  - ⇒ Shift in role of existing agencies (NICE, SMC, AWMSC) to focus on improving access rather than assessing value



## Other conceptual issues

- Product-specific versus portfolio
- One VBP system vs multiple systems (vaccines, ultra-orphan medicines, rare disease medicines, stratified and targeted medicines)
- Proportionality of VBP e.g. budget impact, reimbursement price <= relevant comparator
- WTP for severe or unmet need
- Multiple indications = blended price reflecting differing values for different indications
- Review scheduling (e.g. entry of new comparators)



## Operational issues

- Process of reimbursement price negotiation and reimbursement price agreement
- Non-disclosure and commercial-in- confidence of reimbursement prices or agreements
- Arbitration and appeal processes
- Length of process (EU Transparency Directive requirements)
- Organisational infrastructure, staffing and resourcing levels to operate VBP
- Timing of discussions on value assessment and reimbursement pricing
- Flexibility for first wave of products undergoing VBP



## The case for change....

- *'The development of VBP for new medicines from 2014 provides significant opportunities to both improve patient outcomes through the more appropriate use of medicines and to stimulate the development of the new innovative medicines of the future'*

- ABPI

- *'Better outcomes, greater innovation, a broader and more transparent assessment and better value for money for the NHS are entirely aims for a new system of drug pricing'*

- Cancer Research UK

- *'We...support the Government's proposals to provide pharmaceutical companies with a more stable and transparent system and clearer signals about priority areas of unmet clinical need to ensure research efforts are directed to the best effect and deliver the optimum outcomes for patients and the NHS'*

- EMIG



## Thank you



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## Implications of Adapting VBP to the Emerging Markets: the Experience of China

John Cai, Ph.D., November 5, 2011

• Strategic Advisor on China, Double Helix Consulting (Singapore)

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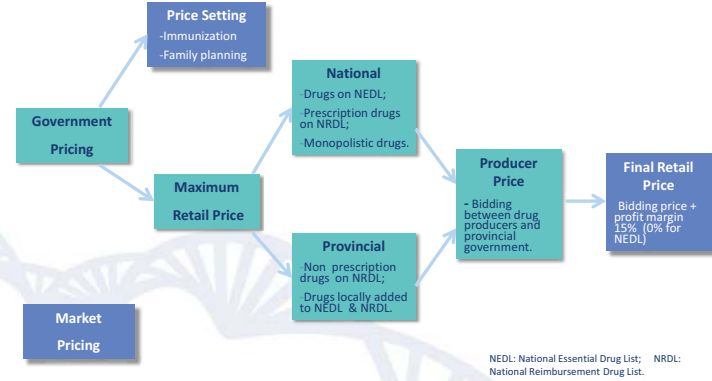
1. **Current Status and Problems of the Drug Pricing Practice and Drug Prices in China**
2. **Positive Trends and Development Toward Value-Based Drug Pricing in China**
3. **Conclusions**
4. **Appendix: Major Government Documents Related to Drug Pricing Practice in China**

## Current Status and Problems of the Drug Pricing Practice and Drug Prices in China

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## Types and Stages of Drug Pricing Process in China

Government price setting accounts for 20% of drug categories and 80% of total drug expenditures



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## Government Drug Pricing Methodology in China

- **“Cost-based pricing”** (reasonable production cost + reasonable profit margin) for the **representative drug (the popular one clinically) in a chemical category**
  - ⇒ Social average cost: reported by drug producers;
  - ⇒ Profit margin considers drug quality, economic development level, purchasing power, and supply and demand. (“Independent Pricing Track”: higher profit margin allowed for “premium drugs”).
- **“Relative pricing ratio”** (reference pricing) for the **non-representative drugs in a chemical category**
  - ⇒ Applied to the drugs with different amount of chemical compounds, dosage, weight, package, and way of administration;
  - ⇒ Considering production cost, technical level, clinical effectiveness, administration convenience, and treatment costs.
- **“Price bidding”** is used to determine producer price between provincial government and drug producers
  - ⇒ “Anhui Model”: separate “technical bidding” from “economic bidding”, which leads to focusing only on low price;
  - ⇒ “Shanghai Model”: one comprehensive bidding package including price as well as quality, patent status, and technology advantage.
- A profit margin in final retail drug price (15%) is allowed for 2<sup>nd</sup> and 3<sup>rd</sup> tier hospitals to compensate for the loss due to low service prices, while zero profit margin allowed for the essential drugs used in community care clinics.

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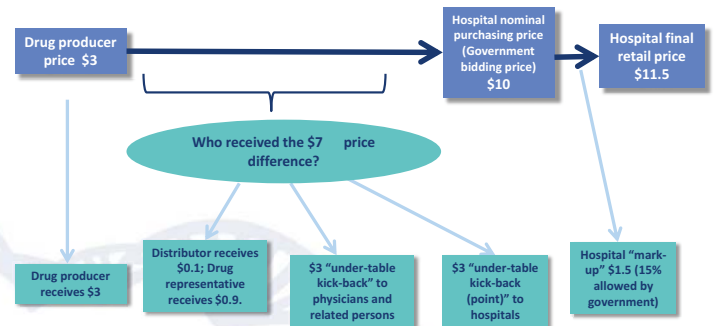
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## Decomposition of Government-Regulated Drug Price in China: An Illustrative Example



Source: Hengpeng Zhu, Yu Yao, Chuang Ou, and Jingwei Chen, “Serious Consequence of the Zero Mark-Up Pricing Policy”, China Health Reform Website, www.chinahealthreform.org.

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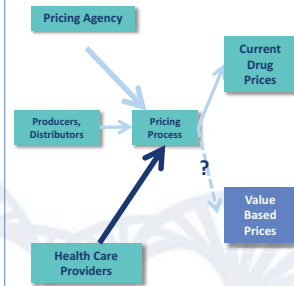
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## Problems of the Drug Pricing Process in China

- **Government-set drug prices do not reflect true cost and quality**
  - ⇒ Drug producers report inflated costs.
  - ⇒ Profit margin is nothing to do with drug quality (cosmetic changes with new label).
- **Low-value drugs often chase out high-value drug in price bidding**
  - ⇒ Price bidding tends to focus on price and ignore other drug features
  - ⇒ Price bidding process is often full of corruption
  - ⇒ Local government protects local product and avoids competition
- **Health care providers have incentive to use higher-priced drugs**
  - ⇒ The low service prices force providers to make up revenues from drugs
  - ⇒ The regulated profit margin in final hospital retail drug price encourage hospitals to chase high bidding price drugs.
- **Although various value factors have been recognized in government drug pricing documents, the actual drug prices are far away from value-based pricing.**

## Barriers to the Value-Based Drug Pricing in China



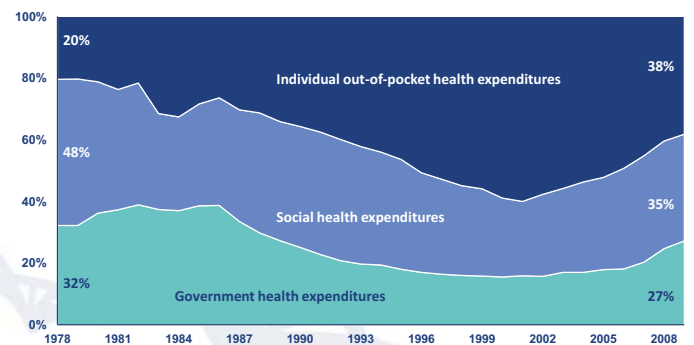
- **Pricing agency:** Is separate from the reimbursement system (MHRSS) which has no role in pricing process.
  - Pricing agency has no strong incentive to pursue rational prices;
  - Corruption and bad policies (e.g. independent pricing, control on hospital profit margin in final drug price).
- **Public hospitals:**
  - Have incentives to pursue high-priced drugs due to the distorted price structure and regulated profit margin in retail drug price.
  - Enjoy monopoly power in a) hospital market (90% of all hospital beds) and b) retail drug market (70% of market share).
- **Drug producers and distributors:** The local government protection and anti-competition practice lead to low scale of economy and low efficiency.
- **Pricing process:** Concrete, operational, consistent and comprehensive measures, tools, and methodologies are unavailable for incorporating values into drug pricing.

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## Positive Trends and Development Toward Value-Based Drug Pricing in China

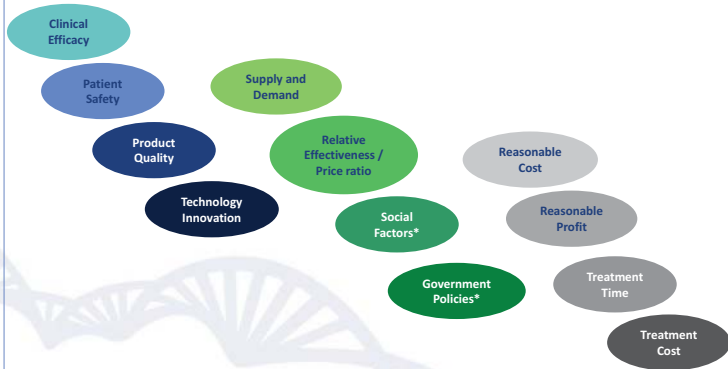
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## Increasing Share of Government and Social Health Expenditures in China Since 2001



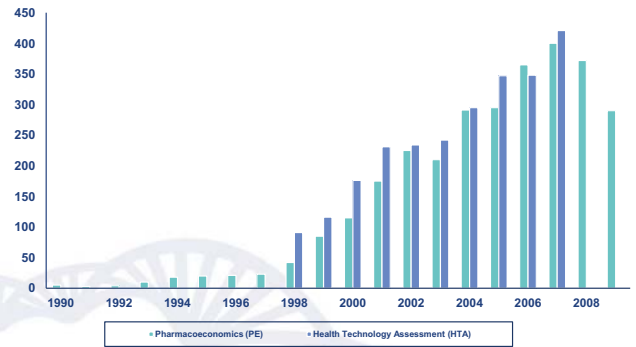
Source: China Ministry of Health: China Annual Health Statistical Book.

## Value Factors Being Recognized in Government Drug Pricing Documents in China Since 2000



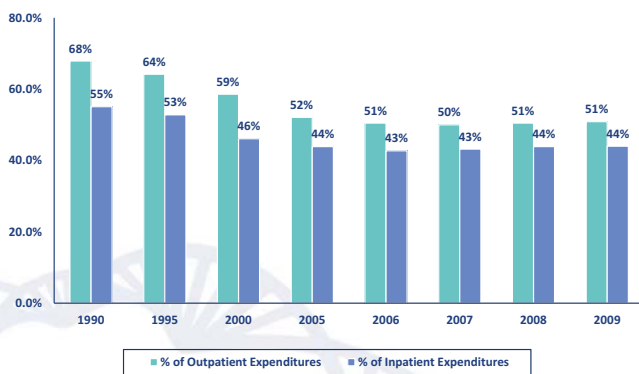
\* Social factors: economic development level, social purchasing power, health insurance coverage.  
Government policies: macroeconomic policy, industry policy, health care policy.

## Increasing Number of Papers on Pharmacoeconomics and Health Technology Assessment in China Since 1990



Sources: Number of published papers on pharmacoeconomics papers in China: Lu Ye, "China's Progress and Trends in Pharmacoeconomics", Fudan University School of Public Health, 2010. Number of papers containing the key word "technology assessment" in medical journals: Yingqun Chen, David Banta, and Zhiliu Tang, "Health Technology Assessment Development in China", *International Journal of Technology Assessment in Health Care*, 25: Supplement 1 (2009).

## Decreasing Share of Drug Expenditures in Outpatient and Inpatient Expenditures in China's General Hospitals



Source: China Ministry of Health: China Annual Health Statistical Book 2010.

## Conclusions

- For China as well as for other emerging markets, the problems and barriers exist not only in the drug pricing process. A system-wide reform package is needed to transform the drug pricing process into a value-based drug pricing process.
- The government itself (incentives, knowledge, management skill, and leadership) is both the major part of the problem and the leading force to initiate this transition.
- Growth of health insurance and payer's power is the critical force to push forward the transition through reforming payment methods and enforcing financial pressure on health care providers and drug producers.
- Information, knowledge, practices and examples generated by research and learned from foreign countries provide important influence to stimulate and facilitate the transition in the emerging markets.

## Thank you

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## Discussion

- Varying definitions of VBP? How do we cope?
- Is VBP a long-term solution? Or additional hurdle?
- Who will be the ultimate beneficiary?

## Thank you

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