

Value-based pricing: a rational approach in Europe!

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Definitions

- Innovation
 - Therapeutic innovation is defined as a new treatment which has demonstrated additional clinical benefits when compared with current standards in properly conducted randomised trials
 - It is difficult to demonstrate 'innovation' through synthesising data from different placebo controlled studies rather than comparative studies
- Value-based pricing:
 - Is defined as assessing whether the additional benefits of a drug are worth the additional costs versus current standards

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Value-based pricing essential given continued resource pressures

- The pressure on health care budgets will grow with ageing populations and the continued launch of new expensive drugs
- Value-based pricing (VBP) for existing drugs can release considerable resources, e.g. Germany with statins and Proton Pump Inhibitors (PPIs). VBP also helps limit the impact of 'demand re-allocation'
- In addition, VBP principles for new drugs will help limit their budget impact conserving resources
- As a result, VBP is essential to help finance increased volumes and new drugs in the future to benefit patient care

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Value-based pricing essential to release resources, e.g. Germany

- Instigation of reference pricing for drugs grouped by comparable pharmacological and therapeutic activities (Level 2) has resulted in considerable savings in Germany, e.g. statins and PPIs

Drug class	Health service costs 2003	Health service costs 2006	% change	Savings	Volume increase (2003 vs. 2006)
Statins	€1091mn	€61mn	-49%	€30mn	49% (DDDs)
PPIs	€1006mn	€91mn	-11%	€115mn	57% (DDDs)

- Savings are comparable to envisaged savings from the OFT proposal in the UK

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Value-based pricing essential to release resources, e.g. UK

- The Office of Fair Trading (OFT) in the UK estimated annual savings of over £570mn (£1 = €1.42) from instigating VBP in selected classes with interchangeable products and generic availability
- The classes or related classes included:
 - Statins
 - PPIs
 - Patients who can tolerate ACE I inhibitors but currently prescribed a sartan
 - Patients currently prescribed similar but more expensive isomers

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Value-based pricing can be applied to three main situations

- The three main situations for applying value-based pricing (VBP) are:
 - Establishing a maximum for originator prices once generics available
 - Establishing a maximum price for existing brands within therapeutically interchangeable groups (Level 2 in Germany) once generics are available in the class
 - Setting transparent principles for valuing innovative new drugs

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Originator prices should be similar to generic prices

- Originator products should be priced similar to generics under value-based pricing principles as no therapeutic differences
- This principle is accepted by manufacturers in the majority of EU countries with patients required to pay any difference between the current reference price for a generic and the originator price, e.g. France, Italy and Poland
- This results in manufacturers typically lowering originator prices certainly initially to compete in the market endorsing this recommendation

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Existing brands in a class only limited premium under VBP principles

- Using our definition, there should only be a limited premium for existing interchangeable brands in a therapeutic class once standards lose their patent
- This reflects the need to balance economy with the need for multiple brands in view of inter-patient variation and often small incremental developments with follow-on products
- Value-based pricing for existing brands is happening across Europe, e.g. Austria, Germany, Italy, Poland, and Sweden
- Proposed reforms for UK and PPIs in Sweden more transparent than pricing schemes in Germany and Italy. Consequently, providing direction in the future

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Proposed reforms in Sweden and UK more transparent

- The proposed maximum reimbursed price for brand PPIs in Sweden is 25% above generic omeprazole (DDD basis); else products delisted. The only exception is NEXIUM in selected cases
- The OFT in the UK is proposing a maximum 50% premium versus current generics for continued reimbursement of interchangeable brands in a class or related classes
 - The UK proposal includes allowances where products not fully interchangeable, e.g. sartans versus ACEI inhibitors where some patients still require sartans to enhance compliance

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Ongoing VBP reforms in Germany and Italy more complex

- In Germany:
 - ❑ The reference prices for products in Level 2 groups are set at the top of the lowest third for products in the class
- In Italy:
 - ❑ The reference price for the class is set at the level where the accumulated number of DDDs consumed is 60% and the accumulated NHS expenditure 50% of the total market
 - ❑ The only exception is where a single active substance accounts for 50% of the total market. Here the reference price is 15% above cheapest active substance
 - ❑ New products exempt if they demonstrate significant health gain versus current standards

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The price premium for new drugs should depend on their degree of benefit

- The premium for new drugs should depend on their level of benefit versus current standards under VBP principles
- Prices are typically derived in EU countries with formal Pricing and Reimbursement systems by first deciding the level of innovation, e.g. Austria and France
- The perceived level of innovation subsequently drives price consideration. However, no defined criteria for classifying the degree of benefit
- Criteria for granting significant price premiums for new drugs will tighten as resource pressures grow. Minimum improvements in outcomes will increasingly become normal

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The level of innovation for new drugs in France is divided into 6 categories

- New drugs in France are assigned an ASMR (Amelioration du service medical rendu – the additional therapeutic benefit versus current standards) score:

ASMR rating	Explanation (versus current standards)
I	Major therapeutic advance
II	Great improvement in effectiveness or side-effects
III	Modest improvement with clear added-value
IV	Minor improvement with only slight benefit
V	Similar product including generics
VI	Negative opinion - not reimbursed

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The level of innovation for new drugs in Austria is divided into 3 categories

- New drugs in Austria are assigned one of 3 major groups:
 - ❑ Demonstrates 'substantial added' therapeutic benefit versus current standards
 - ❑ Demonstrates only 'added benefit' versus current standards
 - ❑ Is similar to current standards
- The number of patients likely to benefit from the new drug is also classified into:
 - ❑ The majority of patients
 - ❑ A defined subgroup of patients

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The level of innovation drives new product pricing, e.g. France

ASMR rating	Typical reimbursed prices for new drugs
I and II	Free pricing - similar to average prices in Germany, Italy, Spain and UK
III and IV	Prices negotiated based on patient benefit and budget impact versus current standards
V	Price reduction - this includes placebo trials

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The level of innovation drives new product pricing, e.g. Austria

Therapeutic benefit for patients	Number of patients treated	Price (acquisition costs) in comparison with listed products
Substantial added	Majority	Higher prices based on average EU prices - Pharmacoeconomic study required
	Subgroup	Higher prices based on average EU prices - Pharmacoeconomic study required
Added	Majority	Maximum 10% higher
	Subgroup	Maximum 5% higher
Equal/ similar		Lower (minimum 10%)

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The criteria for granting significant premiums for new drugs will tighten

- The improvements in patient benefits required to grant significant price premiums for new drugs will necessarily tighten with increased resource pressures
- It is likely these will increasingly centre on demonstrating significant improvements in outcomes, e.g. 6 to 12 months additional survival in advanced cancer patients
- As a result, envisaged only a limited number of new drugs in the future will be seen as major advances commanding high prices
 - Similar to current perceptions by *Prescrire* versus the number of new products annually assigned ASMR I or II by the Transparency Commission in France

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The number of major advances will fall as criteria tighten

- The Transparency Commission in France typically believe up to 8 new products per year are sufficiently innovative to achieve ASMR I or II
- This contrasts with *Prescrire* (French Drug Information Journal) which believed no major advances in 2005

ASMR rating	Typical number of new drugs per year
I	Typically 2 to 3 new products per year
II	Also rare - up to 5 new products per year
III	Typically 15 to 20% of all new products per year
IV	Majority - approximately 50% of new products
V	All generics and limited number new products

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Prescrire believed no major advances in 2005. This will become the trend

Category	Number of new products and indications in 2005
Major therapeutic advance	No drug in this category
Real advance but limitations	One drug in this category
Offers an advantage	4 drugs including Premetrexed for mesothelioma and HERCEPTIN
Possibly helpful	20 drugs or indications
Judgement reserved	2 drugs
Not acceptable	7 new drugs, 9 new indications, and 3 line extensions including Efalizumab in psoriasis, cetuximab, and Duloxetine (Incontinence)

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No single country is ideal. Recommendations based on several reforms

- No single EU country has fully implemented value-based pricing
- However, recommendations can be made by collating ongoing reforms across Europe
- Full implementation of value-based pricing is essential to help finance increased volumes and new expensive drugs in the future to benefit patient care
- VBP should also be in the interests of innovative pharmaceutical companies seeking to reap the financial rewards for their efforts

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No single country is ideal. Recommendations based on several reforms

- The recommendations include:
 - Originator prices reduced to generic prices
 - Maximum 25% premium for interchangeable brands in a class or related classes once generics available. Alternatives include severe prescribing restrictions or delisting
 - Price discount (minimum 20%) where new products only similar to existing standards
 - Premium (up to 10%) versus current brands where new products demonstrate 'added benefit' in comparative RCTs but not substantial therapeutic benefit
 - Average EU prices (up to €30 – 45,000/ QALY) acceptable for major advances supported by pharmacoeconomic arguments

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