

Product Listing Agreements

Experience Overseas

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Outline of Presentation

- Types of product listing agreements (PLAs)
- Assessments of value-added
- Transparency and confidentiality
- Lessons learned

Types of PLAs

- Price/volume agreements
- Pay-for-performance agreements
- Value-based prices

Price/Volume Agreements

- Widely used in France: also Italy, Spain, Australia, others
- Can be simple (ie price goes down as more drug is sold), or complex (ie expected volume is calculated based on 'appropriate use' of the drug)
- Can be important in value-based pricing when a drug has several indications

Pay-For-Performance Agreements

- Typically used when there is uncertainty about the long-term effectiveness of a product, or its effectiveness in patient sub-groups
- Mixed experience in the UK:
 - beta interferon for MS ('failure')
 - bortezomib for multiple myeloma ('success')
- Main concerns include:
 - agreeing on study design
 - problems with, and cost of, monitoring outcomes
 - difficulties in enforcing policies based on study findings

Value-Based Prices

- Different 'value-based pricing' schemes exist in different jurisdictions
- Major differences are in:
 - the method for assessing value-added
 - the extent of transparency in the process
 - whether the prices are kept confidential

UK Value-Based Pricing Proposal

- Would apply to new branded medicines launched from January 1, 2014
- Recognition that new arrangements may be required for already-existing medicines
- The negotiation would consider:
 - the 'basic' cost-per QALY threshold
 - the burden of illness and unmet need that the medicine focuses on
 - the extent of therapeutic innovation
 - the wider societal benefits (eg impact on carers)

Issues Raised by Value-Based Pricing

Defining the dimensions of 'value'

- health gain only?
- other considerations?

Determining the local decision rule

- explicit cost per QALY threshold?
- general rating (eg 0-5), as a guide for price negotiations?

Dealing with multiple indications

- price/volume agreements?
- weighted price?

Determining the level of transparency

- publication of assessments?
- publication of negotiated prices?

Methods for Assessing Value-Added

- QALYs gained
 - Australia, Sweden, UK
- Grading on a scale
 - France, Germany

Some research in progress suggests that the assessments of value-added do not differ much between the various methods

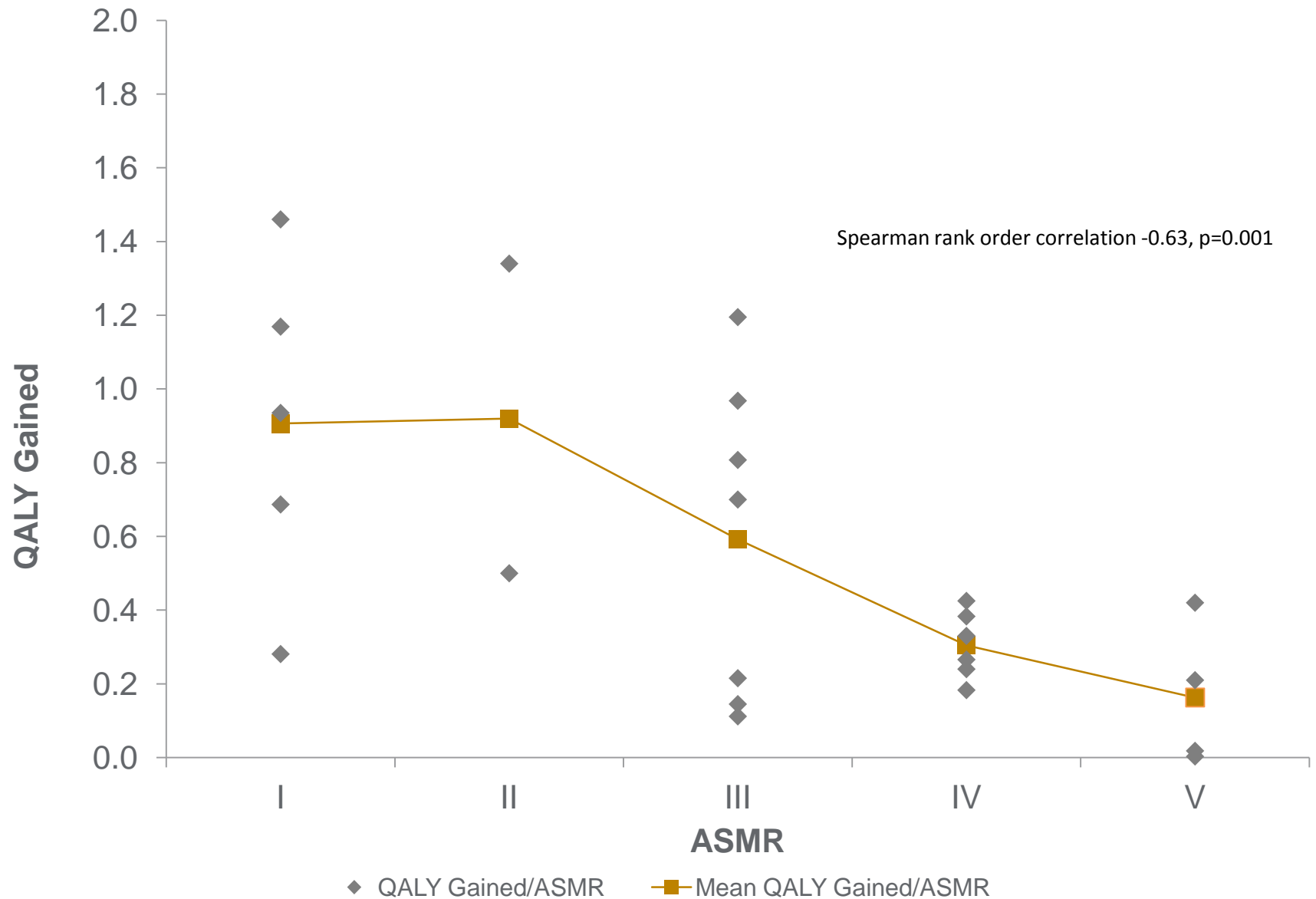
Comparison of the 'British' and 'French' Approaches to Drug Pricing and Reimbursement

- Two contrasting approaches have emerged in Europe for rewarding the added value from drugs
- The 'British' approach (also applied in Australia, Canada, Ireland, The Netherlands and Sweden) relies on an assessment of the incremental cost per QALY, which is then compared with an implicit or explicit threshold
- The 'French' approach (also applied in Germany) relies on a clinical assessment of 'added value', which then serves as a guide for pricing

Study compared the outcomes of the assessment process in the UK and France for 41 anti-cancer drugs

Drummond *et al* *Value in Health* 2012 (Abs)

QALYs Gained vs. ASMR



Transparency of Processes

- Varies by jurisdiction, but those jurisdictions assessing QALYs gained tend to have more transparent processes for assessment
- All jurisdictions bring other factors into the subsequent price negotiation; sometimes these factors are made explicit, sometimes not

Confidentiality of Prices

- *France*- confidential
- *Germany*- originally made public; then promises of confidentiality; currently the situation is unclear
- *Sweden*- confidential, as negotiated by the county councils
- *Australia*- confidential
- *UK*- confidential through patient access schemes; future not clear

Examples of Early UK Patient Access Schemes

- b-IFN and glatiramer for multiple sclerosis – 2002
 - Prospective cohort – managed by DH
- Bortezomib for multiple myeloma – 2007
 - Money back guarantee based on response (M-protein)
- Ranibizumab for AMD – 2008
 - Dose capping scheme (<14 injections per eye)
- Erlotinib for SCLC – 2008
 - Cost capping scheme (same overall cost as docetaxel)
- Sunitinib for advanced RCC – 2009 DRAFT
 - First time EOL guidance informed decision
 - 1st cycle of treatment free to NHS patients
- Lenalidomide for multiple myeloma – 2009 DRAFT
 - Dose capping scheme (<26 cycles/2yrs)

More Recent Patient Access Schemes

- Vast majority of schemes are simple discounts
- In a recent review of NICE technology appraisals for cancer drugs, patient access schemes were applied in 53% of cases (increasingly so for more recent drugs)
- Confidentiality is maintained outside the UK, although some information is shared within the UK

Lessons Learned

- Value-based pricing/reimbursement is the most appropriate framework within which to view all these schemes
- Pay for performance schemes and price-volume agreements can play a role in specific cases
- Transparency in processes is desirable, particularly in the assessments of value-added
- Confidentiality of prices is required in order to secure the most favourable deals and can be defended from a broader public health perspective