

**Antitrust Regulation and IP in the
Pharmaceutical Sector**

**The Pharmaceutical Price
Regulation Scheme
Outcomes and implications of the OFT Study**

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Views expressed are my own and not the OFT's

Relevance of PPRS Market Study

- 8 **Example of a competition advocacy approach**
 - 8 Not antitrust
 - 8 Recommendations to Government on amending policy framework
- 8 **So why discuss PPRS study today?**
 - 8 Case study: key importance of policy framework for considering effects in pharmaceutical antitrust cases
 - 8 Potential implications of reform : which types of issues may become more important in the future?

Overview of study

8 Remit

- 8 Assess whether PPRS best means of meeting its objectives – VfM and incentives to invest
- 8 ... or whether case for reform

8 Timetable

- 8 Launched September 05
- 8 Published February 07
- 8 Government response expected mid-June 07

What is the PPRS?

- 8 **£8n pa spent in UK on branded drugs prescribed in NHS. PPRS means of influencing price**
- 8 **Profit controls**
 - 8 Cap and floor on company profits on sales to NHS
 - 8 Rules for allowable costs
- 8 **Price controls**
 - 8 Freedom of pricing up front. Subsequent restrictions on increasing prices
 - 8 Periodic price cuts imposed. 7% in 2005. Can be delivered through 'modulation'

PPRS is a demand side instrument

- 8 **Not a truly regulatory measure. Attempt to exercise buyer power in purchase of prescription drugs**
 - 8 Structure of demand atypical
 - 8 PPRS certainly atypical!
- 8 **Important implications**
 - 8 No argument that exercising buyer power undermines IP rights. IP rights cannot guarantee revenue in a market
 - 8 Argument arises from conflation of role of state as purchaser and regulator

Focus on dynamic incentives

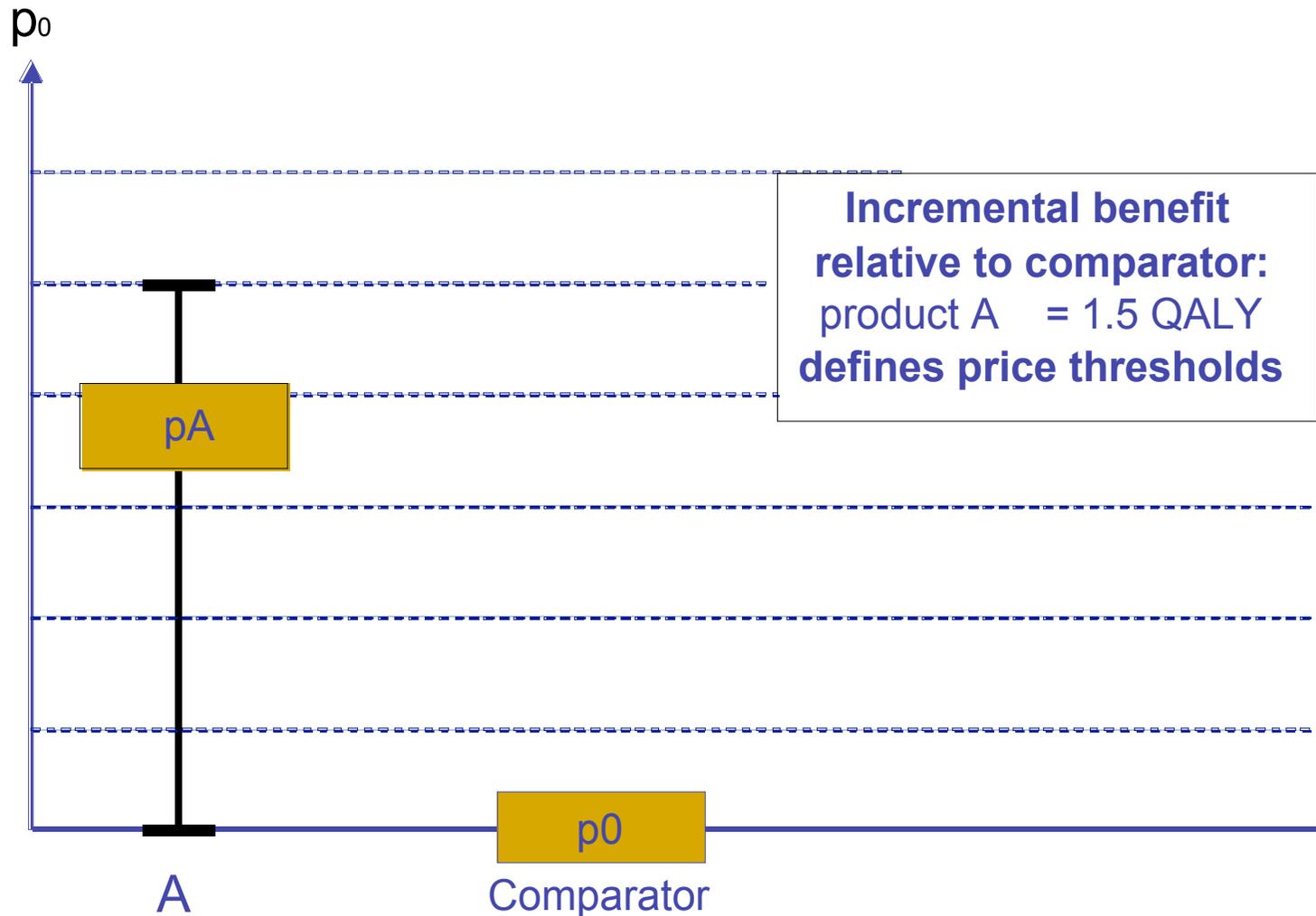
- 8 So should we ignore effects on innovation?
- 8 R&D global common cost but UK sales only c. 4% of world demand. But
 - 8 At least 12 countries (c. 25% of world market) peg prices to reference basket that includes UK
 - 8 Used informally in negotiations as well
- 8 UK prices likely to influence incentives to invest in drugs
- 8 Focus on static and dynamic efficiency legitimate

Main concerns with current scheme

- 8 **Neither profit nor price controls take account of value of drugs: implications for VfM and incentives to invest**
 - 8 Profit cap ill suited to an innovative sector. Plus practical difficulties (downplayed in recent years)
 - 8 Price cuts more important but again blind to value of drugs – winners and losers. Plus sustainability
 - 8 Portfolio effects (and margin differences) potential to distort competition
- 8 **Practical implications: over £600 m in 2005 could have been used more cost effectively (snapshot). Benefits for patients and innovative companies from reform**

Recommendation

- 8 **That Government work towards reform of PPRS replacing current profit and price controls with a value based approach to pricing**
- 8 **On patent**
 - 8 Fast track ex ante assessment and five yearly ex post reviews
 - 8 Flexible price structure – rebates etc. to reflect different value in different indications
- 8 **New system would free resources to improve patient access to treatments and give companies stronger incentives to invest in the most useful drugs**



Cost/QALY equalised at maximum thresholds

Key challenges

8 Questions of principle and implementation

- 8 Definition of value, including varying benefits in subgroups and indications
- 8 Information requirements
- 8 Choice of comparators

8 Principle adopted in each case balancing static and dynamic efficiency

- 8 Not just 'division of rent' – nothing to say about overall level of prices
- 8 ... but how to target investment in most beneficial areas

Relation between recommendations and pharma antitrust cases

- 8 **Parallel trade: recommendations consistent with ‘emerging consensus’**
- 8 **Generic entry: recommendations may increase importance of antitrust work to ensure generic entry is not impeded**

Parallel trade

- 8 **Standard arguments: supply in country of origin, prices in countries of destination, innovation. An empirical question**
- 8 **Option of allowing rebates in lieu of price changes can lead to a ‘win / win’ outcome for payers and companies**
 - 8 “in designing and implementing a pharmaceutical pricing scheme it is not beholden on either public purchasers or manufacturers to ensure that sufficient price differences across Europe are maintained to sustain an industry designed to arbitrage against those differences”
- 8 **Does not imply that actions to restrict parallel trade necessarily consistent with competition law. Case by case**

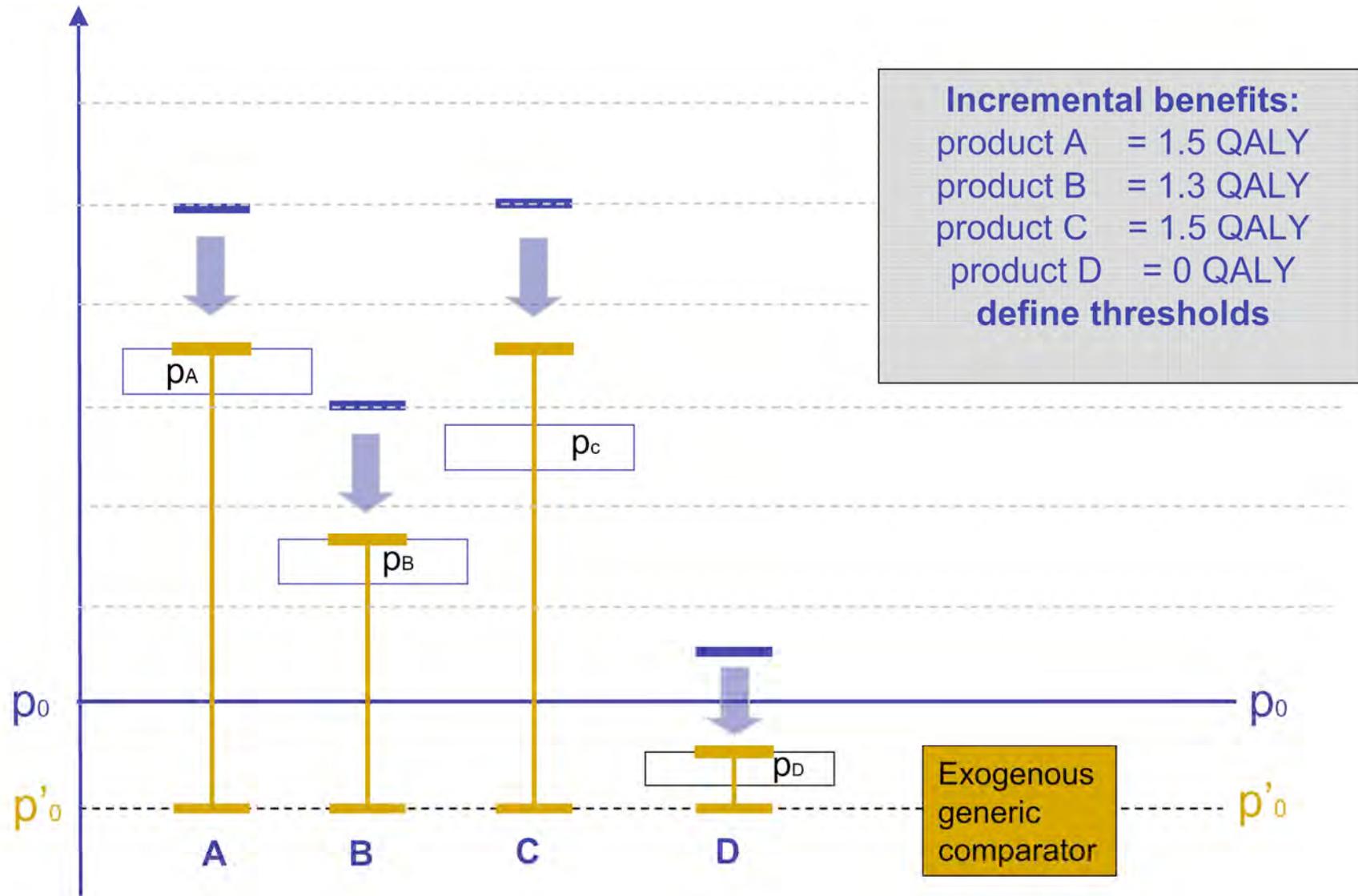
Generic entry

8 Important role played by generics in recommendations

- 8 On-patent brands earn a premium if can demonstrate benefits over generic
- 8 Both VfM and predictable long run incentives – encourages innovation in areas of unmet need. Does not penalise simultaneous innovators
- 8 In UK generics prices set exogenously. Anchor to pricing system

8 Might lead to greater incentives for incumbent to forestall generic entry

- 8 Growing antitrust focus on measures to delay generic market entry may be sustained in the future



Conclusions

- 8 **Antitrust work in area of pharmaceuticals needs to be based on close analysis of regulatory environment**
- 8 **PPRS study recommendations may require increasing antitrust focus on generic entry**
- 8 **Market studies increasingly important instrument**
 - 8 Reform of regulatory, policy environment may be most effective solution to market problems
 - 8 Broad scope - address issues of dynamic innovation that could not be tackled through antitrust work
 - 8 Drawbacks – powers
 - 8 In future increasingly flexible about choice of instruments?