

EU competition issues in the healthcare sector

John Markham

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Overview of topics

- **How does market definition work?**
- **Update on pricing abuses: recent EU cases**
- **A major issue for the UK health sector: stock allocation**
- **Most topical issue for pharma sector: limiting generic competition**

How does market definition work?

Market definition - pharma

- Geographical
 - API – potentially global
 - end product – national
- Product
 - OTC v Rx; research markets
 - demand substitutability – e.g. indications, side effects, dosage, means of administration, prescription practice, reimbursement, price
 - ATC level 3 a starting point
 - applied in Czech case law
 - may be ATC 4
 - AstraZeneca case (covered later)
 - dominant for PPIs (level 4)
 - non-dominant for anti-ulcer (level 3)

Market definition – medical devices

- Geographical
 - usually at least regional, often national
 - effect of reimbursement?
- Product
 - demand substitutability
 - less problematic than pharma

Update on pricing abuses: recent EU cases

Update on pricing abuses

- Companies in health sector often have dominant products
- The rules on abusive pricing are increasingly clear
- ...but mismatch between flexible economics (EC 200 abuse guidelines) and strict law in ECJ judgments
- New investigations arguably show a shift from price to access as the next main abuse issue

Two 2012 ECJ cases on pricing abuse

<i>Post Danmark</i>	March 2012	Postal services	Useful clarification of uncertain point – can dominant companies negotiate different deals with their customers?
<i>Tomra</i>	April 2012	Reverse vending machines	Strict application of old law – good chance that loyalty discounts offered by a dominant company are abusive

A major issue for the UK health sector: stock allocation

Stock allocation – why is it a policy issue?

- Supplier perspective: quotas needed
 - regulatory obligation to supply domestic market
 - excessive exporting may affect bottom line
- Member State healthcare perspective: quotas not too bad
 - threat of product shortages through excessive exports
 - PT market may increase counterfeits
- Pharmacy perspective: quotas bad
 - business flexibility
 - responding to patient need
- EU competition law perspective: quotas suspect
 - protection of cross-border trade and pricing arbitrage within EU
 - reflected in Member State competition policy
- UK and Czech Republic are low-price exporting countries

Summary of law on stock allocation

	Sub-dominant	Dominant
Agreement to limit grey trade?	Restriction of competition	Restriction of competition
No agreement to limit grey trade?	No restriction of competition	Must sell ordinary amounts to customers

Most topical issue for pharma sector: limiting generic competition

The policy background

- Worldwide decline in innovative medicines coming to market
 - blockbuster medicines losing patents
 - increase in generic medicines (65% of UK medicines are generic)
- European Commission Sector Inquiry
 - wide allegations concerning strategies to exclude generics
 - final report July 2009
 - weak conclusions...
 - ...but a number of live enforcement cases have resulted
- Against the background of AztraZeneca case on generic foreclosure
 - now before ECJ
- Part of a general trend in recent cases to focus on use of IP or regulatory process to foreclose market access to competition

EU cases on limiting generic entry since the Sector Inquiry

Servier/generic companies	July 2012 statement of objections	Patent settlement (pay for delay)
Lundbeck/generic companies	July 2012 statement of objections	Patent settlement (pay for delay)
Johnson & Johnson/Novartis	October 2011 announcement	Contractual arrangements
Cephalon/Teva	April 2011 announcement	Patent settlement for sleep disorder drug
Servier	July 2010 statement of objections	Misleading information during sector inquiry
General monitoring of settlement agreements	July 2011 second Commission monitoring report	Settlement agreements generally – further report expected