PRICES IN THE PHARMACEUTICAL SECTOR

The Italian experience

INTERNATIONAL WORKING GROUP ON RESEARCH OF COMPETITION ISSUES IN THE PHARMACEUTICAL SECTOR

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COMPETITION POLICY IN THE PHARMA SECTOR

EXCESSIVE?

THE ASPEN CASE

CONDITIONS

COMPETITION POLICY IN THE PHARMA SECTOR

The traditional issue: tension between innovation and exclusionary practices

- Not undermine incentives for costly R&D and innovation
- Prevent illegitimate use of IP rights to create barriers to entry

COMPETITION POLICY IN THE PHARMA SECTOR

Recent cases: exploitative practices, unfair prices

- Aspen case in Italy (2016)
- Pfizer and Flynn Pharma in UK (2016)
- Comparative analysis of drug prices by FAS Russia (2017)
- Open investigations by the European Commission and the Competition Commission of South Africa (2017)

EXCESSIVE?

When is a price excessive?

- Comparison with productive cost (sale price vs cost of production)
- Comparison across competitors (price charged by dominant player vs price charged by non-dominant player)
- Comparison across time (price in different points in time)
- Geographic comparison (price in other geographic markets)

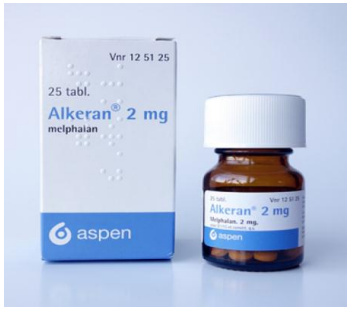
EXCESSIVE?

- Price unfair in itself?
- Price unfair when compared…
- Legitimate reasons may justify prices above the benchmark/competitive price: cost of production (and x-inefficiency) or consumers perception (i.e. willingness to pay…).
- The burden of proof is on the dominant player

THE ASPEN CASE

Portfolio of antineoplastic drugs purchased by Aspen from GSK in 2009:

- long-off patent but still used in the treatment of severe blood cancers (leukemia, mieloma)
- prices entirely reimbursed by the NHS (so called A class drugs)
- prices in 2013 date back to first marketing authorization (‘50s and ‘60s)



THE ASPEN CASE

CONDUCT

In March 2014 Aspen obtained substantial price increases following negotiation with the pharma regulator (AIFA)

Product name	Active ingredient	% increase in price
Alkeran	melphalan	+1540%
Alkeran inj	melphalan	+257%
Leukeran	chlorambucile	+1166%
Purinethol	mercaptopurine	+465%
Tioguanina	tioguanina	+306%

Aspen threatened leaving the Italian market if the regulator did not accept the price increases

THE ASPEN CASE

DOMINANT POSITION

- Lack of effective competition in the 4 relevant markets (active ingredients) - monopoly
- Lack of potential competition – no incentive to entry in light of the scarce sales volume and entry costs
- Weak countervailing buyer power - inelastic demand for life saving drugs; AIFA needed the drugs; no agreement would result in inclusion in charged drugs with unregulated price

FIRST TEST: gross margin

- *Ex ante* prices - direct costs
- Gross margin (%) - total indirect costs (%)

- Prices before the increase already granted a margin in line with Aspen average

- Hence, price increase led to unreasonable excess of prices on the economic value

THE ASPEN CASE

SECOND TEST: cost plus

- prices – cost plus (direct costs + portion of indirect costs + 13% Return On Sales)

- Excess between 100% and 400%
- Well above previous abusive cases

THE ASPEN CASE

Case-specific elements of unfairness of prices

- absence of economic justifications for increase
  - no increase in production or distribution costs
  - no innovative efforts or R&D expenditure
- absence of non-cost related factors of improvement in quality or service
- absence of substitutes driving to inelastic demand
- threat on the Pharma Regulator AIFA

THE ASPEN CASE

The Regional Administrative Court upheld the decision (August 2017)

- Aspen did not need to raise prices of the off-patent drugs to recoup its investment, purely commercial move
- Correct application of the European Court of Justice's United Brands test: profit margin and cost-plus analysis
- Drugs are old, cost little to produce, and that there was no justification for the increase

CONDITIONS

- High and non-transitory barriers to entry leading to a monopoly or near monopoly
- Exclusive or special rights
- No effective means to eliminate entry barriers
- No sector regulator competent (or powerful enough) to regulate prices
- No countervailing power of powerful buyers

CONDITIONS

The lack of reliable data or the complexity of the analysis cannot justify a superficial or inconclusive assessment