AUTORITÀ GARANTE DELLA CONCORRENZA E DEL MERCATO

UNFAIR PRICING: THE ASPEN CASE

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AGCM AND EXCESSIVE PRICES

Very few decisions on excessive prices

A306 Veraldi/Alitalia (airlines), 2001: **non-infringement decision**. Two benchmarks: the pricing behavior of a non-dominant competitor and the costs of an efficient player. Evidence was deemed insufficient to conclude that the prices charged by the incumbent were unfair.

A376 ADR/Tariffe aeroportuali (handling Rome) and A377 SEA/tariffe aeroportuali (handling Milan), 2008: benchmarks provided by sectorial regulation.

A480 - Incremento prezzo farmaci Aspen, 2016: **infrigement decision**

MAIN FACTS

Aspen, a pharmaceutical group operating mainly in the provision of generics, bought in 2009 from GSK a product portfolio of antineoplastic drugs, Alkeran, Leukeran, Purinethol and Tioguanine (the "Cosmos portfolio").

The Cosmos portfolio products are used in the treatment of severe blood cancers (leukemia, mieloma).

First marketing authorization dates back to the '50s and '60s.

Production and distribution:

- Third-party producers
- Distribution in Italy: buy-and-sell model

In Italy, the Cosmos portfolio generated a turnover of [5-10] mln Euros.

The drugs are entirely reimbursed by the Italian NHS ("class-A drugs"), being considered essential for patients.

NEGOTIATION PROCESS (1/2)

Request for reclassification

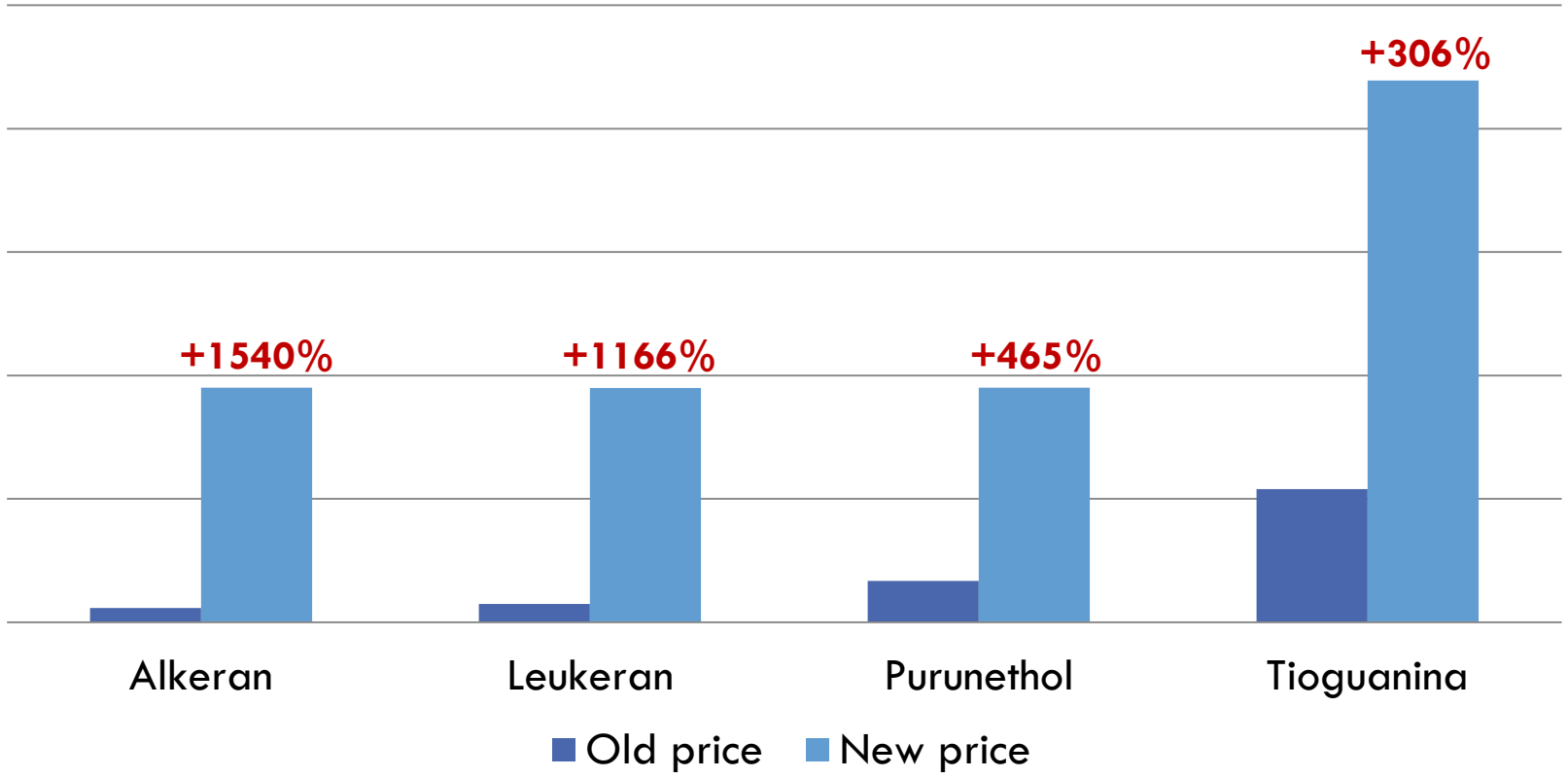
- From the "A class" (where the price for the patient is totally reimbursed by the NHS) to the "C class" (where companies are free to set the price and drugs are not reimbursed)
- AIFA rejected the "unprecedented" request for reclassification, considering the drugs "essential" since they lacked any therapeutic alternative for certain categories of patients

Request for price revision

- negotiation process between the pharmaceutical companies and the Regulator (AIFA)
- The revision of an approved price is admitted, with companies being asked to document changes in production costs, improvements in the quality/safety of the drug.
- If an agreement on the price is not reached, the product is listed in Class C, i.e. it ceases to be reimbursed by the Italian NHS

PRICE INCREASES

In 2013 Aspen submitted to the regulator (AIFA) a request for price increases ranging from 300% to 1,500%



NEGOTIATION PROCESS (2/2)

During the price revision process, Aspen:

- did not document increases in production or distribution costs as required by Italian regulation, despite reiterated requests by AIFA
- used its stock allocation mechanism to artificially create scarcity in the Italian distribution system and increase uncertainty for product delivery
- threatened to withdraw products from the Italian market if AIFA did not accept the price increases

In March 2014, AIFA accepted the price increases.

THE PROCEEDINGS

In November 2014, AGCM launched a formal investigation into a suspected breach of art. 102 TFEU by Aspen in relation to the price increases of the Cosmos portfolio products

In October 2016, AGCM issued its final decision, finding that Aspen had infringed competition law by charging excessive and unfair prices in Italy for its Cosmos portfolio products

AGCM fined Aspen €5 million

AGCM's decision was upheld by the lower administrative court

Appeal is pending in front of the higher administrative court

RELEVANT MARKETS AND DOMINANCE

Relevant markets

- Four relevant product markets at ATC5 level (chemical substance) with a national scope
- No therapeutic alternatives for certain groups of patients in specific phases of their illness, i.e. for a given kind of therapy (at home)
- Other authorized drugs to treat the same pathologies, based on different active ingredients, can only be used in hospitals and have more severe side effects

Dominant position

- Aspen is the only supplier
- Despite no patent pending, no (threat of) entry by generics
- No effective countervailing buyer power by the regulator
  - The regulator cannot impose prices
  - If no agreement, drugs cease to be reimbursed by the Italian NHS (unacceptable outcome for AIFA given the nature of the drugs)

(SCREENING TEST)

Semi-regulated market

- Regulated negotiation process
- Given the nature of the drugs, and the outside options, no effective countervailing power by the regulator

Barriers to entry

- Small economic dimension of the markets
- Technical time necessary to register a generic drug and the lack of MA requests
- High preference for therapeutic continuity

No innovation

- The Cosmos drugs were developed in the 50s and 60s
- No innovation or specific quality-enhancing investments by Aspen

THE LEGAL TEST

In order to establish that a price is unfair under point (a) of Article 102 of TFEU it is necessary to demonstrate that the price charged by the dominant company has no reasonable relation to the economic value of the product/service supplied.

This excess could, *inter alia*, be determined objectively if it were possible for it to be calculated by making a comparison between the selling price of the product in question and its costs of production.

A two-stage test to ascertain if

(i) the price is excessive; and

(ii) the price is unfair ("in itself or when compared to competing products").

[*Case 27/76 – United Brands Company v. Commission [1978] ECR 207*]

EXCESSIVENESS

Gross margin contribution	Ex-ante prices for each product had a positive contribution margin, which was in line with Aspen average one Contribution margin(s) ≥ total indirect costs (as a % of sales)	
Price-cost margin	Difference between prices and Cost Plus: direct costs + allocated common costs + rate of return on sales **Excess:** [100-150]% – [350-400]% [100-150]% – [250-300]%	▪ Internal cost data acquired in dawn raids ▪ Common costs: comprehensive and allocated in proportion to direct costs ▪ Trademarks costs ▪ Profitability measured as ROS ▪ Robustness to various assumptions

UNFAIRNESS

1. Inter-temporal comparison of prices

- Ex-ante prices were already covering costs
- Magnitude of the price increases
- Prices largely in excess of Costs Plus

2. No economic justifications for price increases

- No increases in (direct) costs
- Not even the need to recoup investments for purchasing the Cosmos portfolio: IRR >> WACC

3. Lack of benefits to patients/NHS

- No improvement in quality or in the level of service to the NHS or patients

4. Nature of the drugs and the company

- Antineoplastic drugs with no possibility for patients to shift to alternative medical treatment
- Patents had long expired
- Generic company with no R&D investments

5. Aspen's conduct during negotiations

- "Unprecedented" request for reclassification of life-saving drugs
- Artificial shortage of the products in the Italian distribution network
- Threat not to serve the Italian market

"ECONOMIC VALUE"

Cost-based benchmark

- United Brands: the excess could, *inter alia*, be determine objectively if it were possible for it to be calculated by making a comparison between the selling price of the product in question and its cost of production
- While appreciating the difficulties… do not seem to present insuperable problems
- Cost-based benchmarks are widely used in antitrust (predation, margin squeeze, loyalty discounts,…)

Demand-side factors

- buyers' willingness to pay

Price benchmarks

- Historic prices
- Geographic price comparison
- Prices of other products
- Prices that would prevail under conditions of normal and effective competition

"*It is clear that the "economic value" is a legal rather than an economic concept.*"

"*[…] the economic value of a product is highly fact-specific and very much a matter of judgment*"

FOLLOW-UP

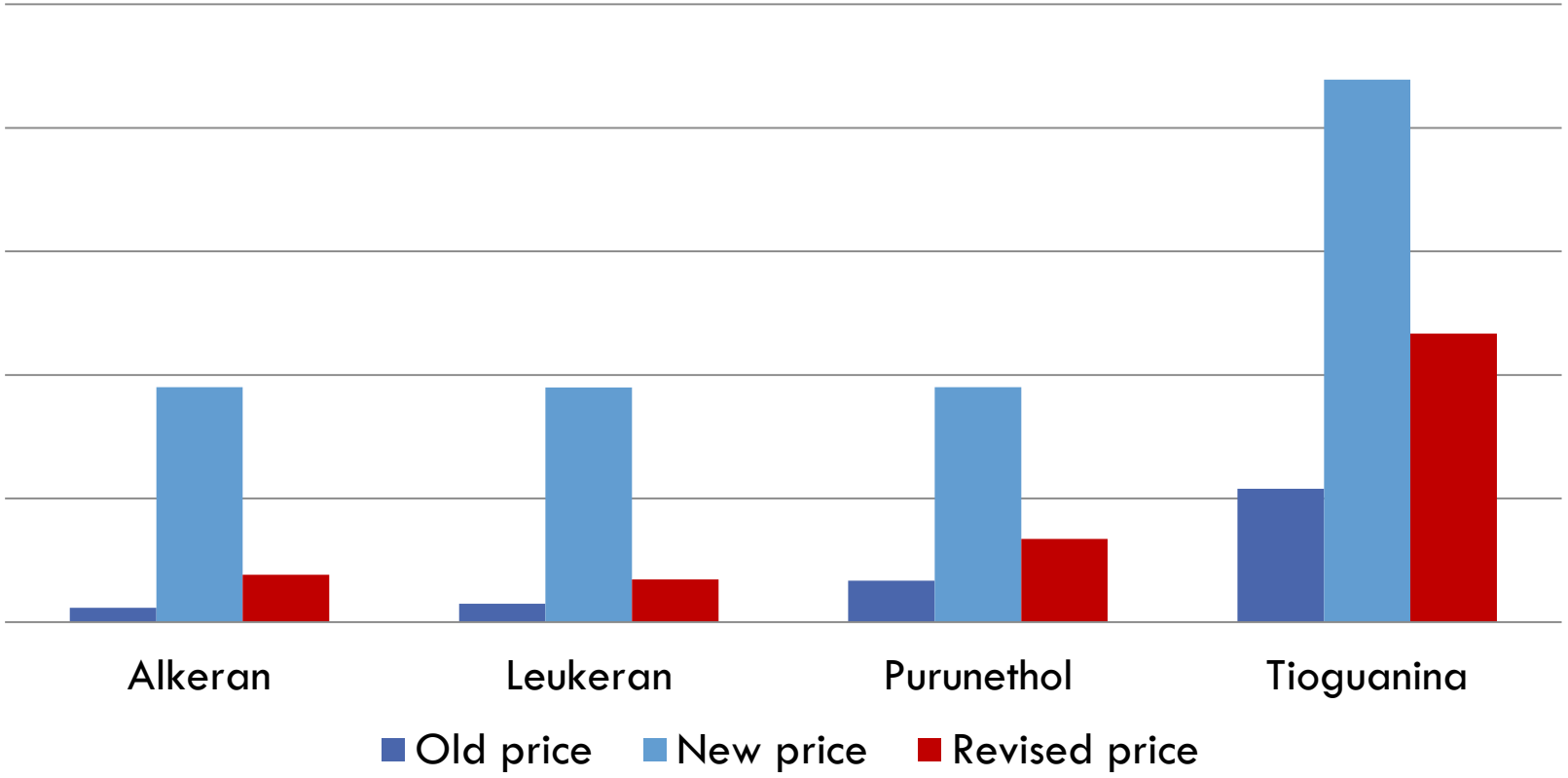
Cease and desist order (September 2016)

- Aspen had to stop its abusive conduct and inform the Authority, by 60 days after the decision, of the action adopted to comply.
- The Decision did not tell Aspen what prices to set and how to set them: it is for Aspen to charge prices which have a reasonable relationship with the economic value of the products and are compatible with EU and Italian competition law.

Non-compliance proceedings (March 2017 → June 2018)

- In April 2018, after receiving the SO, Aspen submitted all the relevant information (supplier contracts, costs related to quality & safety etc.) and reached an agreement with AIFA.
- Price increases relative to ex-ante prices (retroactively) reduced to [70%-200%]
- Proceedings closed with no sanction

REVISED PRICES



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http://en.agcm.it/dotcmsDOC/pressrelease/A480_eng.pdf

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