

# Excessive Pricing Cases in the UK and Italy: the *Aspen* case

***Claudia Desogus***  
**Case handler**  
**Pharma Directorate**  
**Italian Competition Authority**


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# The facts (1)

- In **2009 Aspen acquired from GSK** the trademarks and the marketing rights over some anticancer products used for the treatment of leukaemia, lymphoma, myeloma, etc. (the «**Cosmos**» drugs):
  - Leukeran (*chlorambucil*)
  - Alkeran (*melphalan*)
  - Purinethol (*mercaptopurine*)
  - Tioguanine (*tioguanine*)
- The Cosmos drugs are **essential for specific groups of patients** (children and elderly) affected by specific types of cancer (absence of therapeutic alternatives in Italy).

## The facts (2)

- In **2013 Aspen** requested the Italian Medicines Agency (IMA) to **pass from the A and H classes to the C class** ('delisting')
  - C Class  **prices freely set by producers and fully paid by patients**
- **IMA refused based on essentiality** of the medicines and **asked Aspen to formulate a price proposal**
- **Aspen** asked for a **price increase considered unbearable for the NHS.**
- **Aspen** insisted on a recategorization or on substantial upward revision of prices and **threatened of reducing the supply or withdrawing the drugs concerned.**

## The facts (3)

- In **2014 Aspen** obtained a price increase of **300% to 1500%** as compared with the initial prices charged

	<b>Vecchio prezzo ex factory*</b>	<b>Nuovo prezzo ex factory</b>	<b>Vecchio prezzo al pubblico</b>	<b>Nuovo prezzo al pubblico</b>	<b>delta % prezzo al pubblico</b>
<b>Alkeran</b>	€ 3,51	€ 57,62	€ 5,80	€ 95,10	1540%
<b>Alkeran inj</b>	€ 31,46	€ 149,87	€ 69,21	€ 247,35	257%
<b>Leukeran</b>	€ 4,54	€ 57,53	€ 7,50	€ 94,95	1166%
<b>Purinethol</b>	€ 10,19	€ 57,62	€ 16,82	€ 95,10	465%
<b>Tioguanina</b>	€ 32,71	€ 132,96	€ 53,99	€ 219,44	306%

Source: ICA; IMA

# The Infringement Decision

- **September 2016:** according to the Italian Competition Authority (ICA) **Aspen abused its dominant position** by *imposing excessively unfair prices through an instrumental and distorted use of the price re-negotiation procedure*
  - **very aggressive negotiation strategy** towards the IMA
  - strong pressure on the regulator through the **credible threat of reducing or withdrawing the drugs concerned**
  - **Very weak regulator:** national rules provides that if negotiation on prices between the regulator and the undertaking concerned are unsuccessful, drugs are automatically classified in the C class

# The Remedies and the Appeals

- **ICA imposed on Aspen a fine of over Euro 5 million**
- **Aspen had carry out all behaviours necessary to define fair prices** with reference to the Cosmos drugs and **refrain from future behaviours analogous** to those object of the infringement decision
- **February 2017:** Aspen's request for interim measures rejected by the First Instance Administrative Tribunal
- **July 2017:** ICA's decision has been upheld by the First Instance Administrative Tribunal

# The non-compliance proceedings

- **March 2017:** the ICA opened the non-compliance proceedings
- **June 2017:** interim agreement between IMA and Aspen:
  - retroactive reimbursement to the NHS of half of the difference between the 2013 prices and the 2014 (“unfair”) prices
- **June 2017 - February 2018:** unsuccessful negotiation between Aspen and IMA, which rejected Aspen’s request to:
  - include trademark acquisition costs among the production costs relevant to justified the price increase
  - use EU weighted average prices rather than 2013 prices as a starting point for the negotiation
  - use the prices of therapeutic alternatives as benchmarks
- **March 2018:** ICA’s Statement of Objections alleged a dilatory strategy by refusing to provide relevant information to establish fair prices

# The new negotiated prices

- **April 2018:** Aspen submitted all the relevant information and reached an agreement with IMA

	PUBLIC PRICES* in €			
	2013 Prices	March 2014 (Unfair) Prices	19 April 2018 Prices	Δ% 2014-2018
ALKERAN TABLETS	5.8	95.1	19.24	-80%
ALKERAN INJECTION	69.21	247.35	116.68	-53%
TIOGUANINA	53.99	219.44	156.39	-29%
PURINETHOL	16.82	95.1	33.62	-65%
LEUKERAN	7.5	94.95	17.34	-82%

- **June 2018:** the ICA closed proceedings with no sanctions
  - The application of the new prices is retroactive, to the date of the infringement decision
  - Estimated public savings: roughly **€ 8m per year**, on the basis of the public prices net of legal discounts and selective reductions

# The methodology

# The excessiveness

## FIRST METHOD: gross margin

- The ICA calculated the difference between the *ex ante* Prices and the Direct Costs.
- The resulting Gross Margin in % of sales was compared to the Total Indirect Costs in % of sales to conclude that:
  - 1) prices before the increase already granted a margin in line with Aspen average.
  - 2) therefore, price increase % ranging between 300% and 1500% of initial prices conducted to an excess of prices on the economic value.

# The excessiveness

## SECOND METHOD: Cost Plus

- Cost Plus = costs + Reasonable Rate of Return
- Costs = variable direct costs (COGS) + quota of the fixed costs + quota of the indirect costs reasonably attributable to the products
- **RRR = Return On Sales** (13% - the average ROS realized in 2013-2014 by the two main generic companies operating worldwide).
- The difference between the Cost Plus and the prices applied by Aspen generated an excess in % of the Cost Plus ranging **from 100% to almost 400%**.

# The unfairness

## LACK OF REASONABLE RATIO BETWEEN PRICES AND ECONOMIC VALUE

- **Absence of any economic justifications** for such an increase:
  - no increase in production or distribution costs documented by Aspen
  - no need to recover innovation investments
- **Absence of any non-cost related factor** leading to an improvement in quality or in the level of service to the NHS or patients
- **The nature of the drugs and characteristics of Aspen**
  - life-saving drugs
  - no patent coverage
  - no R&D expenditures

# The unfairness

## STRATEGIC PRESSURE ON THE REGULATOR

Aspen adopted a comprehensive strategy to put pressure on IMA:

- **strategic request for drug reclassification** from A class to C class: Aspen was aware of IMA's impossibility to accept (essential medicines for the treatment of cancers);
- **threat of withdrawing the drugs from the Italian market**, if IMA did not accept the proposed prices;
- «artificial» scarcity in the Italian distribution system: a shortage of the Cosmos drugs in the Italian distribution system was observed despite the absence of any production problems; this artificial shortage, generated through Aspen's Europe-wide stock allocation mechanism, was aimed at influencing IMA's decision making process

# Aspen's defences

- **Excessiveness** - the chosen RRR is inadequate, since it is an average ROS, unrelated to the characteristics of the specific product. Aspen's internal ROS should be considered.
- **Excessiveness** – indirect cost allocation should be based on sales profits rather than on costs of goods sold.
- **Excessiveness** – a price comparison at the international level should be performed.
- **Unfairness** – demand elasticity (i.e. willingness to pay) should be taken into account.

## ICA's counterarguments: the choice of the RRR

- The chosen RRR equaled to a ROS of **13%** (average of the sector) and yielded an excess between **[100-150]%** and **[350-400]%**.
- *But even changing this assumptions on the RRR...*
- ROS **13%+trademarks**: excess between **[100-150]%** and **[300-350]%**.
- ROS **[15-20]%** (**Aspen's ROS**): excess between **[100-150]%** and **[250-300]%**.
- ROS **[15-20]%+trademarks**: excess between **[50-100]%** and **[200-250]%**.

# Other counterarguments

- **Excessiveness** - sales profits are influenced by the prices and their use as allocation key determines a potential flaw in the calculation of costs if prices are excessive
- **Excessiveness** - undisputed that cost of goods sold represents the best approximation of the inputs used in the realisation of a good
- **Excessiveness** – a price comparison would be flawed by the potential excessiveness of prices charged in other EU countries (Aspen applied a pan-European strategy)
- **Unfairness** - the economic value cannot be determined by taking into consideration consumers' willingness to pay, since lacking therapeutic alternatives the latter tends to infinite, potentially justifying any price increase.