



BACKGROUND

LEGAL FRAMEWORK

IMPLEMENTATION BY
COMPANIES

ACTIONS BY
WHOLESAHLERS

LESSONS FROM
PRACTICE

Parallel trade and free pricing

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Trade, 10 February 2010**



BACKGROUND

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BACKGROUND

- Spain has traditionally been an "exporting" country in parallel trade of medicinal products due to the low prices approved by the authorities.
- Parallel trade has caused serious problems of supply and lack of availability for certain products in the Spanish market.

LEGAL FRAMEWORK

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LEGAL FRAMEWORK (1/5)

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- By means of act 55/1999 (in force as from 1 January 2000) a legal reform was made to the Spanish Medicinal Products Act in order to state that the ex-factory price approved by the authorities only refer to those products which:
 - are financed by the National Health System, and
 - are dispensed in Spain.



LEGAL FRAMEWORK (2/5)

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- In relation to the interpretation of this amendment, the Ministry of Health issued a communication dated 14 February 2000, which states:

"The governmental intervention is limited not only to the medicinal products authorized, registered and financed by public funds, but also, amongst these, only to those which are going to be dispensed in national territory. Therefore, those medicinal products which are not going to be dispensed in the Spanish territory have free price."



LEGAL FRAMEWORK (3/5)

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- In 2003, Royal Decree 725/2003 further amended the Spanish Medicinal Products Act in order to clarify that a medicinal product has been dispensed on Spain when *"it has been made available to the patient through a legally authorized pharmacy based in the territory"*.
- Furthermore, Royal Decree 725/2003 established the obligation for wholesalers to communicate to the Ministry of Health the number of units financed by the NHS which are sold to pharmacies or to other wholesalers.



LEGAL FRAMEWORK (4/5)

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BACKGROUND

- These reforms have remained in the wording of the new Medicinal Products Act (29/2006):

LEGAL FRAMEWORK

IMPLEMENTATION BY COMPANIES

“Art. 90.2. (...) Ministry of Health and Consumer Affairs, will be in charge of fixing, by reasoned decision and based on objective criteria, the maximum industrial price for medicinal products and medical devices which are going to be covered by the National Health System, financed with public funds, and which are supplied in the national territory subject to official medical prescription.”

ACTIONS BY WHOLESALERS

LESSONS FROM PRACTICE

“Art. 90.5. The industrial prices of medicinal products shall be free for those products which are not financed by public funds (...)”



LEGAL FRAMEWORK (5/5)

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“Art. 87. Wholesale distributors must, on such terms as regulations shall determine, report to the Autonomous Community in which they have their registered office and to the Ministry of Health and Consumer Affairs the number of units supplied and units returned, stating batch and recipients – whether retail pharmacies, hospital pharmacy departments or other wholesale distributors – irrespective of their Autonomous Community of domicile.”



IMPLEMENTATION BY COMPANIES

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- This legal framework allowed pharmaceutical companies to set up free price systems, which caused in several cases a rearrangement of the relationship with wholesalers.
 - Pfizer
 - Janssen-Cilag
 - MSD
 - Lilly
 - Sanofi-Aventis
 - Novartis



IMPLEMENTATION: PFIZER'S STRATEGY (1/3)

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BACKGROUND

- A new commercial policy was notified to the DGC in May 2001:

LEGAL FRAMEWORK

IMPLEMENTATION BY COMPANIES

- Invoicing at free price but applying a provisional discount for the difference between the authorized ex-factory price and the free price.
- Wholesalers should certify the dispensation in Spain within 6 months or reimburse to Pfizer the amount of the discount.

ACTIONS BY WHOLESARLERS

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IMPLEMENTATION: PFIZER'S STRATEGY (2/3)

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- Wholesalers refused to collaborate and Pfizer had to claim payment before the courts, which in some cases was not successful due to the fact that Pfizer was not able to prove that the medicinal products were dispensed outside Spain.
- In 2002 and 2004 Pfizer reduced the number of wholesalers to which supply medicinal products. Wholesalers filed complaints before the competition authorities and the courts for refusal of supply without success.



IMPLEMENTATION: PFIZER'S STRATEGY (3/3)

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- In November 2004 Pfizer announced its will to implement direct distribution system and communicated to wholesalers the termination of their relationship as from June 2005.
- In April 2005 Pfizer unilaterally decided to withdraw its intention to apply the direct distribution system and proposed a new contractual free pricing frame to a limited number of wholesalers.



IMPLEMENTATION: JANSSEN'S STRATEGY

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LESSONS FROM
PRACTICE

- In September 2006, after the approval of the new Medicinal Products Act, JC sent a letter to wholesalers announcing the termination of their commercial relationship.
- Selected wholesalers were proposed to enter into a new contractual frame which included a free pricing system.



IMPLEMENTATION: MSD's STRATEGY

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ACTIONS BY WHOLESARLERS

LESSONS FROM PRACTICE

- With a three month notice, MSD notified the implementation of the free price system to all its wholesalers in November 2006, following the approval of the new Medicinal Products Act.
- MSD has not terminated any relationship with any distributor, nor has it entered into any new written agreement.



IMPLEMENTATION: LILLY'S STRATEGY (1/2)

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LESSONS FROM
PRACTICE

- In August 2003 Lilly notified to distributors its intention to apply a free pricing system, according to which:
 - Lilly would invoice at authorized ex-factory price, and
 - would later make the corresponding adjustments according to the information obtained from the authorities (Art. 87)
- Lilly had to distribute medicinal products directly to pharmacies in some areas due to the lack of availability of the products.



IMPLEMENTATION: LILLY'S STRATEGY (2/2)

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LESSONS FROM
PRACTICE

- Due to the lack of implementation of the notification system by the authorities, Lilly notified the need to establish new commercial free pricing conditions, where Lilly invoices at free price and eventually makes adjustments to the prices according to the information provided by distributors.
- Lilly has not terminated any agreement with wholesalers, which remain verbal.



IMPLEMENTATION: SANOFI'S STRATEGY

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ACTIONS BY
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LESSONS FROM
PRACTICE

- In June/July 2007 Sanofi announced the termination of the commercial relationships with distributors.
- New agreements were signed with a reduced number of distributors where a free pricing system is established.



IMPLEMENTATION: NOVARTIS' STRATEGY

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BACKGROUND

- Novartis sent termination letter to all distributors but did not implement a free price system.

LEGAL FRAMEWORK

IMPLEMENTATION BY COMPANIES

- Novartis entered into new agreement with a limited number of wholesalers which include Novartis' right:

ACTIONS BY WHOLESARLERS

- Not to accept all orders from distributors.
- To terminate the agreement if wholesaler does not duly supply the pharmacy offices in the territory.

LESSONS FROM PRACTICE



IMPLEMENTATION: CRONOLOGY

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BACKGROUND

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ACTIONS BY WHOLESARLERS

LESSONS FROM PRACTICE

	Free pricing	Number of wholesalers
Pfizer	May 2001	25
Janssen-Cilag	March 2007	32
MSD	February 2007	68
Lilly	August 2003	41
Sanofi-Aventis	January 2008	29
Novartis	Not applied	40



IMPLEMENTATION: COMMON FEATURES

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BACKGROUND

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IMPLEMENTATION BY
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ACTIONS BY
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LESSONS FROM
PRACTICE

- Common features of the free pricing system:
 - Pharmaceutical companies invoice at free price.
 - Wholesalers are reimbursed the difference between the authorized ex-factory and the free price when wholesalers prove that the product is financed by public funds and is dispensed in national territory.
 - The data provided by wholesalers are codified in order for manufacturers not to have access to confidential commercial data of pharmacy offices or other wholesalers. Such data are managed by an independent third party.



ACTIONS BY WHOLESALERS

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BACKGROUND

- Actions for double pricing.

LEGAL FRAMEWORK

- Actions for concerted practices.

IMPLEMENTATION BY COMPANIES

- Actions against the Spanish Medicinal Products Act 29/2006 (EAEPC filed a claim before the European Commission as of 29 February 2008).

ACTIONS BY WHOLESALERS

LESSONS FROM PRACTICE



ACTIONS AGAINST DOUBLE PRICING (1/7)

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IMPLEMENTATION BY COMPANIES

ACTIONS BY WHOLESALERS

LESSONS FROM PRACTICE

- FEDIFAR filed a claim against Pfizer's first free price system before the EC: rejected due to lack of Community interest.
- EAEPC filed a claim on 17 October 2005 against Pfizer's second free price system before the EC: rejected due to lack of Community interest.



ACTIONS AGAINST DOUBLE PRICING (2/7)

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BACKGROUND

LEGAL FRAMEWORK

IMPLEMENTATION BY
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ACTIONS BY
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LESSONS FROM
PRACTICE

- Spain Pharma denounced Cofares and Pfizer for an alleged agreement not to export medicinal products. EC transferred the case to the Spanish authorities (CNC) where the free pricing system was analyzed as obiter dicta in resolution as of 21 May 2009.
- EAEPD also filed a claim before the CNC against Pfizer, Janssen-Cilag, Lilly, MSD, Sanofi-Aventis and Novartis on 17 October 2007. The CNC rejected the claim by means of resolution dated 14 September 2009.



ACTIONS AGAINST DOUBLE PRICING (3/7)

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BACKGROUND

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IMPLEMENTATION BY
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ACTIONS BY
WHOLESARLERS

LESSONS FROM
PRACTICE

- Grounds of resolution of the CNC dated 21 May 2009 and 14 September 2009:
 - The denounced companies do not establish double price, but a sole price which is transformed to the authorized ex-factory price when the legal conditions are met.
 - The ex-factory price approved by the authorities (lower than the free price) is imposed on the grounds of public interest (reduction of public expenditure). Therefore, it must only affect those products able to benefit from public funding.



ACTIONS AGAINST DOUBLE PRICING (4/7)

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IMPLEMENTATION BY
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LESSONS FROM
PRACTICE

“It would not have any sense that the price fixation by the Spanish government on the basis of public interest criteria was extended to other territories or that the products intended to be sold in other countries were affected by the authorized prices fixed in Spain, which would limit the manufacturers’ liberty in an unjustified manner.”



ACTIONS AGAINST DOUBLE PRICING (5/7)

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ACTIONS BY
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LESSONS FROM
PRACTICE

- The Spanish constitution recognizes the right to freely establish prices (applicable also to medicinal products) and it can only be limited exceptionally and by reasons of general interest.



ACTIONS AGAINST DOUBLE PRICING (6/7)

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LESSONS FROM
PRACTICE

- The CNC considers the EC Decision on the Glaxo case (8 May 2001) not relevant because:
 - Important legislative reforms have taken place in Spain since the Glaxo case.
 - The Glaxo Decision is subject to judicial review.
 - The EC has repeatedly ruled that these cases lack Community interest.



ACTIONS AGAINST DOUBLE PRICING (7/7)

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ACTIONS BY
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LESSONS FROM
PRACTICE

- Information systems do not affect competition because the manufacturer only receives codified data, not being able to identify the clients of wholesalers.
- The selection of wholesalers is made based on objective and non-discriminatory criteria.
- Taking into account that wholesalers are free to distribute products from any manufacturer and to sell to pharmacies or to other wholesalers, manufacturers must have the liberty to design the net of distribution they deem convenient for the purpose of maintaining an adequate supply of medicinal products in the market.



ACTIONS AGAINST CONCERTED PRACTICE

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BACKGROUND

- CNC resolutions as of 25 September 2008 and 14 September 2009.

LEGAL FRAMEWORK

IMPLEMENTATION BY COMPANIES

ACTIONS BY WHOLESALERS

LESSONS FROM PRACTICE

- The free pricing systems implemented by each company differ in time and in the performing strategy.
- The coincidence in the mechanisms to obtain data from wholesalers is due to need to know the final destination of the products and the need to maintain the confidentiality of the distributor's commercial information, as required by law.



LESSONS FROM PRACTICE (1/2)

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LESSONS FROM
PRACTICE

- Pharmaceutical companies can choose the wholesalers to which supply product, provided the criteria of selection are objective, non-discriminatory and non-predatory (those which are able to guarantee an adequate coverage of pharmacies and hospitals).
- Free pricing systems are permitted. They are not considered to be double price.



LESSONS FROM PRACTICE (2/2)

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- Collaboration from wholesalers is needed, taking into account that the system of notification to the authorities of the units sold by distributors has never been implemented in practice.
- Codification system is necessary to impede access to confidential data from wholesalers or pharmacies.
- Agreements with wholesalers preferably not including non-compete obligations for wholesalers.



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End of presentation

Thank you for your attention