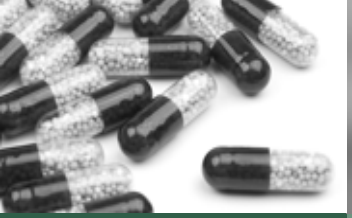
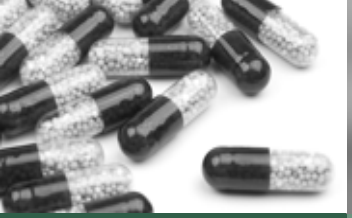


On-Line Seminar on RD 177/2014

Jordi Faus

3 April 2014



Introduction

- Long and complex drafting procedure.

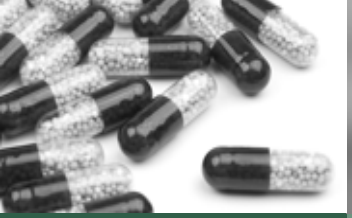
EL PAÍS

SOCIEDAD

Sanidad recupera los precios de referencia tras dos años

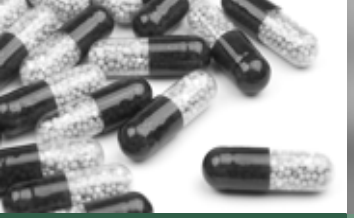
EMILIO DE BENITO | Madrid | 21 MAR 2014 - 18:01 CET

- First regulations implementing the systems of homogeneous groups.
- State Council: complex text that would be convenient to explain in detail in the Preamble.



Preamble

- An unnecessary attack to innovation:
  - *treatments that, for regulation reasons, have privileged situations on the market without competence in prices*
  - *In 10 years "the return or reward of the innovative effort shall be deemed as sufficiently covered"*
- Imposes the idea of prices review after 10 years.
- Clarifies some points (minor prices and lower prices).



Index

1. Reference prices

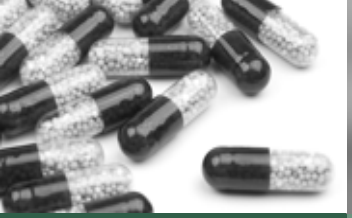
1. Creation of Groups
2. Deletion of Groups
3. Fixing of the Reference Price
4. Special cases
5. Application of the system
6. Coexistence periods

2. Homogeneous groups

1. Rules on dispensing
2. Creation of groups
3. Minor price and lowest price
4. Monthly adjustments of the lowest price
5. Coexistence periods

3. Information Systems

1. The Nomenclator.
2. Information on reimbursement procedures and prices
3. Information on the consumption in hospitals



Reference Prices

1. **Creation of Groups**
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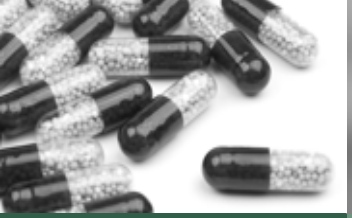
Creation of groups (1/2)

- Same API, same administration route and communication of date of effective commercialization (effective admission for reimbursement).
- Upon the registration of the effective communication, the medicinal products admitted for reimbursement that have not been communicated will be included (A.P. 5).
- The registration in the Nomenclator governs cases of suspension or termination of commercialization.
- A generic or biosimilar is required, unless 10 years of the medicinal product or its main API in the EU and provided that there also exists a medicinal product different from the original medicinal product and its licences.



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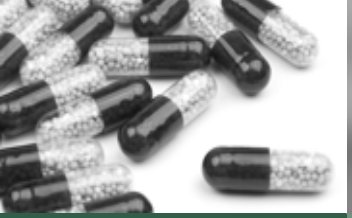
Creation of groups (2/2)

- Concept of licence = the communication of the marketing authorization holder or the local representative is enough.
- If the group is not created and the product has more than 10 years, a procedure to revise the price shall be initiated ex officio in year 11.
- Independent groups for paediatric presentations, clinical packaging, and hospitals' scope (hospital use and dispensed by hospitals' pharmacies).
- Exclusion periods for galenic innovations declared before RDL 16/2012 will be respected.



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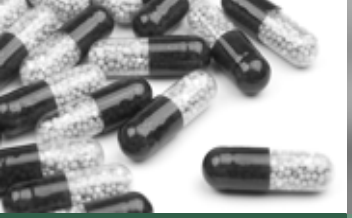
Deletion of groups

- In Ministerial Order yearly.
- Deletion does not affect the Ex-factory Price of the presentations that were included in it.
- A case by case revision of the price can be requested in order for it to be increased over the reference price.



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4. Special cases
5. Appliation of the system
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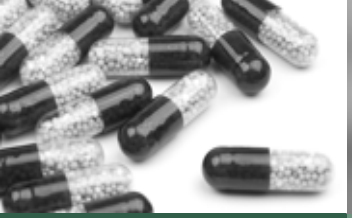
Fixing of the Reference Price

- Lower CTD according to DDD.
- Ref Price = ex-factory price (PVL) commercialized / number of DDD.
- We suppose that the discounts that can be offered under art. 3.6 Law 29/2006 will not be taken into account.
- PVL Ref = Ref Price * number of DDD.



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5. Appliation of the system
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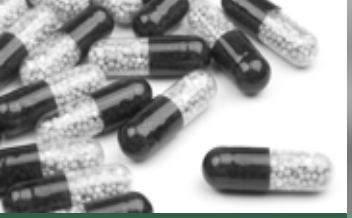
Special cases

- Threshold 1,60 Eur.
- Balanced price in some cases: special doses of active pharmaceutical ingredients, products used for serious diseases, revised due to lack of profitability. Balancing taking into consideration the aggregated invoicing data of the National Health System.
- In any case, PVL never higher than the lowest commercialization price in the EU.
- Obligation to inform and automatic revision ex officio. Questionable compatibility with EU regulations.



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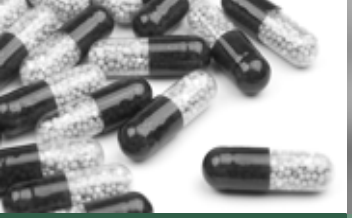
Application of the System

- Annual fixing through Order.
- Cut-off date 1 April, but if the effective commercialization is comunicated during the drafting procedure, it will be included in the process and its PVL will be considered.
- Without intervention of the Inter-territorial Board, because it is a regulated administrative activity, not legislation.
- New presentations are included as their effective commercialization is communicated.



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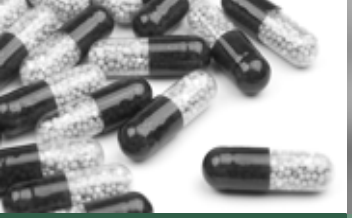
Coexistense periods

- PVLRef is invoiced as from the date established in the Order (Day D Month M).
- Wholesalers can supply stock at higher price until D+20.
- Pharmacies sale at higher price until Day 1 Month M+1.
- Returns only if price on the packaging.
- Pharmacies will invoice the System at higher price until the last day of the month M+1.
- New prices to the Nomenclaror on day 1 of month M+2.



Homogeneous Groups

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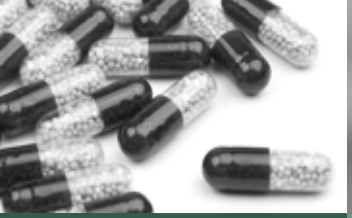
Rules on dispensing

- Prescription Commercial Name = Dispensation Commercial Name unless the price is higher than the Minor Price of its Group.
- Prescription Commercial Name with higher price than Minor Price = The product with lowest price and, if they are equal, a generic.
- Prescription API The product with lowest price and, if they are equal, a generic.
- If there is shortage or urgent need = the ones available by order with lowest price.



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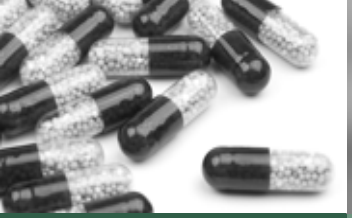
Creation of groups

- Reimbursed presentations, with the same qualitative and quantitative composition in API, same pharmaceutical from or pharmaceutical from group, effectively commercialized and than can be subject to substitution at the moment of dispensation.
- The rule of effective commercialization enters into force on 1 June (Final Prov. 3) upon updating of the Nomenclator (Add. Prov. 5).
- Separation of the ones included only by original and its licences with the same PVL.



Homogeneous Groups

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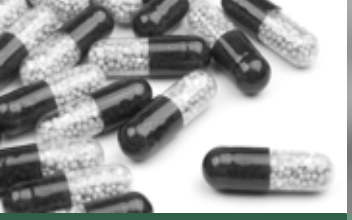
Minor price and lowest price

- Minor price = Group.
- Lowest Price = Individual presentation.
- The Lowest Price becomes the Minor Price every time the Groups are revised quaterly.
- The Lowest Price can keep changing each month according to what the companies notity.
- The Minor Price, as long as not revised, remains as parameter to determine if dispensation by commercial name can me made.



Homogeneous Groups

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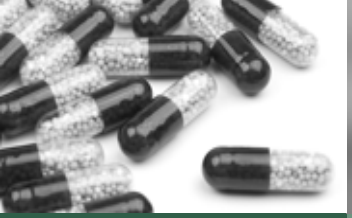
4. **Monthly adjustments of the lowest price**
5. Coexistence periods

Monthly adjustments of the Lowest Price

- Reduction request without changing the NC are admitted between day 5 of each month M-1 and day 4 of each month M.
- Requests are published and there are 3 business days for withdrawal.
- Publication of the minor prices within the first 10 business days of the month M.
- Transfer to the Nomenclartor on day 1 of month M+1.
- “as regards minor prices" the reduction shall be 10%. Application in practice in case of lowest prices pending to be specified. Criteria of the CNMC.



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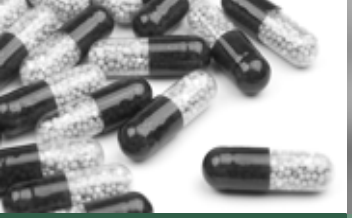
Coexistence periods

- Pharmaceutical companies supply at new price on day 10 of month M.
- Wholesalers issue invoices with the new price from day 20.
- Pharmacies dispense with the new price on day 1 of month M+1.



Information Systems

1. **The Nomenclator**
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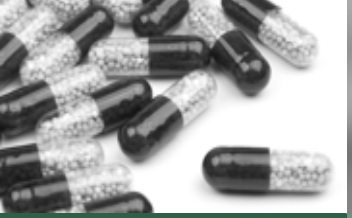
3. **Information on the consuption in hospitals**

The Nomenclator (1/2)

- Official Data Base for the management of the reimbursement plab of the NHS but that includes information about all medicinal products authorized.
- Very detailed information including:
- Información muy detallada incluyendo:
  - Situation of the offer to the NHS.
  - Date of effective commercialization.
  - Maximum reimbursement price.
  - Commercialization price.
  - Notified price.
- Monthly update, cut-off date day 20.



Information Systems

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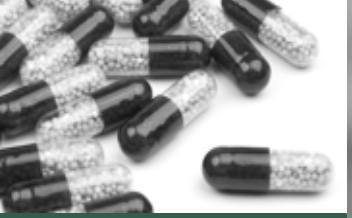
The Nomenclator (2/2)

- Access in order to apply the reference price system and the system of homogeneous groups.
- Currently, access limited to:
  - Public administrations involved in the management of the reimbursement plan of the NHS.
  - General Board of Official Associations of Pharmacists.
- Ministerial Order will regulate the access of companies and other entities. Criteria CNMC vs. principles of Law on Transparency that enters into force in 2015 (2016 in the Autonomous Communities without their own law).



Information Systems

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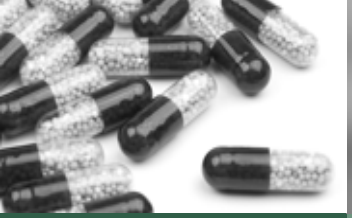
Information on reimbursement procedures and price

- Electronic management of the procedures.
- Access limited to CIPM members.
- Access to person concerned depends on whether the Ministry considers opportune to approve an order or not.



Information Systems

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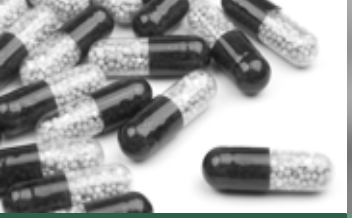
Information on the consumption in hospitals

- Imposes obligations to the relevant public administrations.
- Information about the number of packages or units.
- Identification via National Code.
- It does not require to communicate prices, discounts or other conditions.
- Monthly communication.
- Access limited to the public administrations.



Conclusions

- A complex text with some unanswered questions.
- Dark zones in diverse matters.
  - Minimum threshold subject to EU price.
  - Prices review post 10 years.
  - Deletion of groups does not affect the PVL.
  - Lower flexibility as per the imposition of the DDD that the law no longer requires.
  - etc... etc... etc...
- Many questions can be asked in particular cases.