Pharmaceutical Sector in Brazil: Regulation and CADE’s analysis

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Sector’s Regulation

Background:

- Before 2000: Control of profit margin;
- Between 2000 and 2003: Gentlemen’s agreement established between the country and pharmaceutical companies;
Sector’s Regulation

- **Chamber of Medicines (CMED)**
  - Deliberate and establish directives for the regulation of the pharmaceutical sector.

- **Policy of ceiling prices.**
  - Pharmaceutical companies must practice prices under the maximum price established by CMED for each medicine.
  - Annual readjustments, based on the price of inputs and productivity of the sector.
  - Three types of ceiling prices: i) Factory Price (PF) for hospitals and retailers; ii) Maximum Price to consumers (PMC) to pharmacies and; Maximum Price to the Government (PMVG) to public bids

*The list is released each year on ANVISA’s Website.
CADE’s analysis

- Many cases analyzed in 2000
  - CADE applied the rule of and defined the relevant market based in the definition of the active ingredient of the medicines
  - Identification of the Relevant market, based in the therapeutic definition of each medicine and the drug active ingredient;
  - Criteria of definition based in the Anatomical Therapeutic Chemical – ATC
CADE’s analysis

- **Prospective analysis**

- Studies elaborated by CADE’s Department of Economic Studies:
  - 08700.002883/2015-00 Analyzed the prices of medicines charged by pharmacies
  - 08700.004219/2015-97 Analyzed the prices of orthoses, prostheses and medicines charged by hospitals to health insurance plans

- Technical Note No 41
CASE Eli Lilly

- Administrative Proceeding No 08012.011508/2007-91
  - Sham Litigation (Defendants: Eli Lilly do Brasil and Eli Lilly and Company)
CASE Eli Lilly

➢ Administrative Proceeding No 08012.011508/2007-91
  Sham Litigation (Defendants: Eli Lilly do Brasil and Eli Lilly and Company)

➢ Conclusion
  ➢ CADE condemned, in June 2015, the companies Eli Lilly do Brasil Ltda. and Eli Lilly & Co. for the practice internationally known as sham litigation. The fine imposed sum BRL 36.6 million
Thank you!

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