



Dissemination of Information April 2010

Dear ECONMED participants:

On this occasion we are pleased to share the report *Medicamentos com patentes de Moléculas no Brasil* launched last March by the Núcleo de Assessoramento Econômico em Regulação (NUREM) within Brazil's Agência Nacional de Vigilância Sanitária (ANVISA).

This study tries to compensate for the scarcity of accessible information databases (primary data) on prices of patented drugs; attempting to provide some reference for the use of academics and policy makers in the public health and intellectual property domain.

It is the first tangible result of a process initiated in January 2009 with the selection of a set of proprietary drugs whose prices are registered with the Câmara de Regulação do Mercado de Medicamentos (CMED)^[6]. This primary source was completed with data of manufacturing companies and the system *Life Cycle* offered by IMS Health^[7]. The prices of the selected drugs were compared with eight national contexts: Portugal, France, Spanish State, Greece, the United States, Canada, Australia, and Italy.

Based on an analysis of the domestic market performance of 96 drugs with molecules with in-force patent in Brazil, marketed in 332 presentations the authors aimed at identifying and discerning patterns in evolution of prices.

Among the results we shall point out:

- A comparison between the price of a generic version to a brand-name on a year-long basis, showed an evolution that in some cases (products under patent 2007-08) would reach a 21.33% increase.
- Identification of 14 drugs whose patent expires between 2009 and 2010 (although the final date of conclusion can be amended by judicial intervention).
- Of the 20 drugs with highest market sales levels Brazil in 2008, 8 are found to be patented^[8].
- The percentage of selected products that are found under patent in Brazil in comparison with the chosen countries ranges from 84.4% in Greece (maximum) to 56.3% of Portugal (minimum). The greatest differences of prices are registered with regard to the United States.

The conclusions could be summarized as:

- The value of expenditure on brand-name products (under patent) in comparison to generic versions with regard to the total pharmaceutical expenditure is 40% higher.
- With less than the 1% of total consumption, the products under patent represent 10% of the expenditures. Generic versions, with approximately 13% of total consumption total represent around 8% of pharmaceutical expenditure.
- Of the total of 96 molecules with in-force patent protection, only one has been the result of national research (Brazilian).

^[6] More information on CMED can be found at <http://www.anvisa.gov.br/monitora/cmed/index.htm>

^[7] More detailed information on the kind of data provided by the *Life Cycle* program of IMS Health can be found at <http://www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnextoid=a0c98fabedf24210VgnVCM100000ed152ca2RCRD&vgnextfmt=default>

^[8] Is to be highlighted that among them there is Renagel, which was the subject of an ECONMED Communications in February.

- 52 United States drugs under patent have a higher price than the rest of countries examined which invalidates the hypothesis that denies reference value to prices provided by the Federal Supply Schedule (FSS) of the Veteran Affairs Department of the United States Government^[9] to consider due to their purportedly artificially low nature.
- The number of drugs whose price was the lowest in Brazil increased from 12.7% before Resolution CMED No. 2/2004 (attached)^[10] was passed, to up to 51.5% after its enactment. **This would amount to demonstrate that the resolution contributed to the decrease of patented drugs in Brazil.**

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^[9] More information at Drug Pharmaceutical Prices <http://www.pbm.va.gov/DrugPharmaceuticalPrices.aspx>

^[10] Resolution CMED No. 2/2004 Introduced the compulsory nature to conduct economic evaluation studies (cost benefit) for any drug considered new or in a new presentation before its introduction to the Brazilian market. 2003-2010 CMED resolutions are accessible at <http://www.anvisa.gov.br/monitora/cmed/index.htm>