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# ANALYSIS OF MEDICINES DISPENSED BY COURT ORDER IN THE COURT OF RIO DE JANEIRO: THE APPLICATION OF SCIENTIFIC EVIDENCE IN THE DECISION-MAKING PROCESS

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# *Introduction*

- In Brazil, in spite of advances in Pharmaceutical Services (PS), challenges as to access to medicines persist
- Citizens are increasingly aware of their constitutional rights and using the justice system in effectively pursuing them
- Demand of access to medicines through the Judicial System has been a growing phenomenon
- These medicines range from those that are out-of-stock in the public system to innovations not yet incorporated by the Brazilian Health System (SUS)
- We esteem that the evaluation and use of evidence produced by HTA may be an important support to physicians, health managers and policy-makers in this context.

# *Objective*

To analyze and categorize, in light of scientific evidence, medicines demanded to the State Health Secretariat in the courts of Rio de Janeiro

# Methodology

- Descriptive seccional study
- Study period: from July 2007 to June 2008
- Individual lawsuits brought in the courts of Rio de Janeiro
- Databases used were from the Justice Court of Rio de Janeiro and from the State Health Secretariat
- Market approval was estimated through Health Surveillance Agency (*Anvisa*) package insert online database
- For those medicines not present in publicly financed lists, evidence was based on the *Thomsom Micromedex - Drugdex System* database - available to managers through a government academic site ([www.capes.periodicos.gov.br](http://www.capes.periodicos.gov.br))
- Brazilian MoH Clinical Protocols and Therapeutic Guidelines (*PCDT*) provided additional information on indication

# Results

- For 281 plaintiffs, 804 demands were filed, corresponding to 356 medicines and to 269 pharmaceutical substances.
- Of these, 85 (23,9%) belonged to the 2006 National EML (*Rename*).
- The table below shows the proportion of public funding for demanded medicines.

Tabela 6 - Distribuição dos medicamentos solicitados, segundo presença nos componentes de financiamento da Assistência Farmacêutica. Comarca da Capital - Rio de Janeiro. Estado do Rio de Janeiro, julho de 2007 a junho de 2008.

Componentes				N	%
Excepcional	Básico	Estratégico	Nenhum		
			x	229	66,6
x				69	20,1
	x			37	10,8
		x		4	1,2
	x	x		2	0,6
x	x	x		2	0,6
x		x		1	0,3
<b>Total</b>				<b>344</b>	<b>100</b>

Fonte: TJ/RJ e Central de Mandados da SESDEC/RJ. Elaboração Própria.

- Analysis shows that certain indications are not substantiated by evidence.

**Tabela 9** – Indicações para medicamentos de dispensação excepcional e medicamentos não presentes nas listas oficiais, sua indicação em bula aprovada pela Anvisa e seus respectivos níveis de evidência e grau de recomendação presentes base de dados *Thomsom Micromedex - Drugdex System* (2009). Comarca da Capital - Rio de Janeiro. Estado do Rio de Janeiro, julho de 2007 a junho de 2008.

Medicamentos	Indicação	Bula	Recomendação	Nível de evidência
Sinvastatina	Demência	Não	Classe III	Categoria B
	Diabetes mellitus	Sim	Classe IIa	Categoria B
	Hipercolesterolemia	Sim	Classe IIa	Categoria A
	Hipertensão	Não	Classe III	Categoria B
	Infarto agudo do miocárdio	Sim	Classe IIb	Categoria B
	Insuficiência Cardíaca	Não	Classe IIb	Categoria B
Formoterol + Budesonida	Asma	Sim	Classe IIb	Categoria B
	Doença pulmonar obstrutiva crônica	Sim	Classe IIb	Categoria B
Infliximabe	Artrite reumatóide	Sim	Classe IIb	Categoria B
	Doença de Crohn	Sim	Classe IIa	Categoria B
	Espondilite anquilosante	Sim	Classe IIa	Categoria B
	Psoríase	Não	Classe IIb	Categoria B
Olanzapina	Esquizofrenia (CID 10 F20)	Sim	Classe IIa	Categoria B
	Psicose não-orgânica não especificada (CID 10 F29)	Não	NE*	NE*
	Transtornos globais não especificados do desenvolvimento	Não	Classe IIa	Categoria B
Clopidogrel	Doenças vasculares periféricas	Sim	Classe IIa**	Categoria A**
	Embolia e trombose arterial	Sim	NE*	NE*
	Hipertensão	Não	NE*	NE*
	Infarto agudo do miocárdio	Sim	Classe I**	Categoria A**
	Insuficiência Cardíaca	Não	Classe IIb**	Categoria B**
ácido ursodexocólico	Cirrose biliar primária	Sim	Classe I	Categoria B
	Fibrose hepática	Não	NE*	NE*
	Hepatite granulomatosa	Não	NE*	NE*
	Icterícia neonatal de outras lesões hepatocelulares	Não	NE*	NE*

Fonte: TJ/RJ, Central de Mandados SESDEC/RJ, Anvisa (2009) e *Thomsom Micromedex - Drugdex System* (2009). Elaboração Própria.]

\*Não encontrado na base de dados do Thomsom Micromedex - Drugdex System.

\*\* Utilização para profilaxia de trombose.

# *Analytical categories*

## **1st category**

- Medicines present in publicly financed lists. Indications present in the lawsuit respected national regulations.
- Examples: pegylated interferon + ribavirin for chronic VHC; infliximab for rheumatoid arthritis.
- Demands may reflect failure of management of PS; administrative pathways were not followed.

## **2nd category**

- Medicines in high-cost component for which demand is not compliant with PCDT, even if current evidence substantiates demand.
- Examples: Simvastatin for diabetes as prevention for CV events; formoterol + budesonide for COPD.
- This category is related to lack of updated guidelines or lack of any guideline.

### **3rd category**

- Medicines not yet incorporated by SUS.
- Example: travaprost.
- Alternatives have been present in the National EML since 2006 but have not been publicly financed.

### **4th category**

- Medicines demanded for registered indications, substantiated by evidence and for which alternatives were financed by the system, once they were not first-line treatment options.
- Exemples: infliximab for spondilitis; clopidogrel for MI; losartan for hypertension.
- For these cases, analyzing patient history is an important step as well as balancing risk and benefits of use.



## 5th category

- Medicines not supported by established evidence which warrant cost-effectiveness studies within the health system perspective, among others.
- Examples: ursodesoxicholic acid for primary biliary cirrhosis; analogue insulins for types I and II diabetes.
- In spite of existing evidence, it does not support adoption by health system or clarify pathways for rational use.

## 6th category

- Medicines demanded either for indications unapproved by *Anvisa* or by medicines without market approval or lacking in any evidence supporting their use.
- Examples: sulthiame for epilepsy; olanzapine for para developmental disorders; clopidogrel for peripheral vascular disease; ursodesoxicholic acid for granulomatous hepatitis, cystic fibrosis or other hepatocellular lesions.
- Some demands do not seem to be justified, even if therapeutic alternatives are lacking. No efficacy or safety may be established in these indications and patients may be at risk.

# *Final Comments*

- A vital strategy to counter advance of judicial demands is better management and increased credibility of PS.
- The collaboration between the Judicial System and the Health System is also essential for understanding the origin of demands and to guarantee rights of patients.
- The categories outlined in this study may help the decision-making process in SUS and in the Judicial System.

Thank you

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