

Abstract

Evolution number of litigation cases and expenditure with monoclonal antibodies (MoAbs) (Bevacizumab, Cetuximab and Panitumumab) and tirosine kinase inhibitor (Regorafenib) for the treatment of cancer in Minas Gerais-Brazil: A preliminary analysis from 2009 to 2016

Abstract #89750

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Introduction: The last decade was marked by the widespread use of molecular biological agents in combination with 5-FU / oxaliplatin or irinotecan-containing regimens in the treatment of cancer. Such biological medicines have significantly increased the costs of oncological treatment, leading to concerns about the future sustainability of drug policy and, as a consequence, health systems with universal access to health care. In the case of Brazil, the three MoAbs BEVACIZUMAB(BEVA), CETUXIMAB(CETUX), PANITUMUMAB(PANIT) and one tirosine kinase inhibitor REGORAFENIB(REGORA) compared in this study can only be used by the patient when there is a litigation against the State, since they are not incorporated into the Single System of Health-SUS.

Objectives: To evaluate the evolution number of litigation cases and expenditure with monoclonal antibodies(MoAbs) (Becavizumab, Cetuximab and Panitumumab) and tirosine kinase inhibitor (Regorafenib) for the treatment of cancer in Minas Gerais-Brazil. **Method:** Retrospective descriptive study whose judicial information was extracted from the database of the Minas Gerais State Secretariat - SES-MG. The judicial actions were filed against the State of Minas Gerais for Cancer treatment and refer to the period from January 2009 to December 2016. The study was cut from the judicialized MoAbs (BEVA, CETUX, PANIT) and tirosin kinase inhibitor (REGORA) for the treatment of Colorectal Cancer (CCR). The cost of the treatments was calculated based on the prices of the *Câmara de Regulação do Mercado de Medicamentos* (CMED) ANVISA, taking into account the official dollar exchange rate of the Central Bank on January 31, 2018 and there is no adjustment for inflation. **Results and discussion:** Preliminary results showed that in the period between 2009 and 2016, 1024 lawsuits were filed against the State of Minas Gerais for cancer treatment, making 766 for BEVA, 206 for CETUX, 35 for PANIT and 17 for REGORA . The total cost obtained considering a 6-month overall survival for each patient was \$ 22,260,536. In Brazil, the growing number of litigation and drug costs (BEVA, CETUX, PANIT and REGORA) per year is worrying, considering the increase of 5.100% for judicial actions and 1899% for treatment costs in the period 2009 to 2016 (TABLE 1). **Conclusion:** The exponential increase in lawsuits against the State of Minas Gerais demonstrates the growing pressure on the resources available to attend a reduced number of patients, who are available to judicialize treatments outside universal health coverage, which is already guaranteed right by the Brazilian constitution.

Key words: Litigation, Monoclonal antibody, Cancer, Right to health, pharmaceutical care

Table 1. Evolution number of litigation cases and expenditure on BEVA, CETUX, PANIT and REGORA/ Year in Minas Gerais – Brazil, 2009-2016

Evolution number of litigation cases and expenditure on Beva, Cetux,Panit and Regora/ Year in Minas Gerais – Brazil, 2009-2016										
	2009	2010	2011	2012	2013	2014	2015	2016	Total	% increase 2009 -2016
Bevacizumab	4	10	35	89	147	171	159	151	766	3775
Cetuximab	0	4	13	36	44	36	41	32	206	800

Panitumumab	0	0	0	2	3	6	8	16	35	800
Regorafenib	0	0	0	1	1	6	4	5	17	500
Total cases	4	14	48	128	195	219	212	204	1024	5100
total cost \$ (dolar)	\$220.471,00	\$331.915,00	\$1.122.915,00	\$3.007.052,00	\$4.350.203,00	\$4.507.218,00	\$4.533.324,00	\$4.187.438,00	\$22.260.536,00	1899