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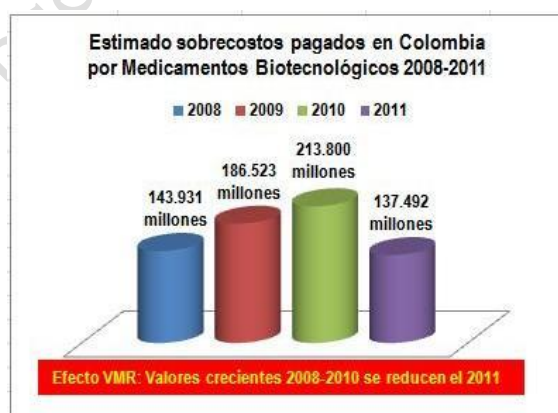
# Observamed

Observatorio del Medicamento - Federación Médica Colombiana

## Accessing biotech drugs in Colombia: 2008-2011 Sales and price comparison with Spain

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## **RECOGNITION**

The Drug Observatory of the Colombian Medical Federation (OBSERVAMED) appreciates the effort and dedication that Dr. Joel C. Miller from Wayne State University School of Medicine, Detroit, Michigan USA, committed to this research "Accessing biotech drugs in Colombia: 2008-2011 Sales and price comparison with Spain", in person in March and April 2012 and later, via the internet.

Thanks to his intelligence and social commitment, Dr. Miller realized very quickly the complex reality of the Colombian Healthcare System and assisted the Colombian Medical Federation in defending the public health in our country.

We are confident that this work will contribute positively to the debate currently underway in Colombia on access to biotech drugs and is in that context that we make public this recognition to work done by Dr. Miller.

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## Table of Contents

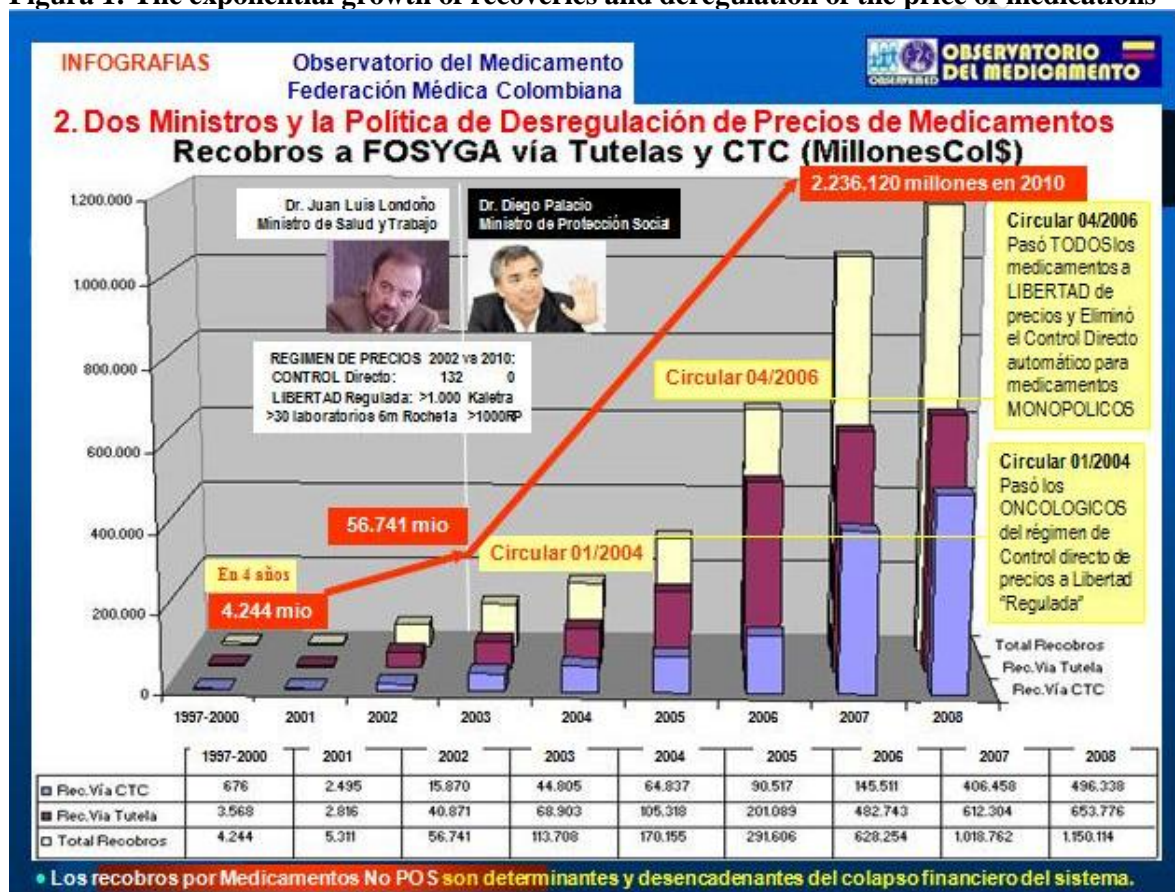
<b>INTRODUCTION.....</b>	<b>5</b>
<b>METHODS .....</b>	<b>9</b>
<b>COMPARISON BY GROUP .....</b>	<b>9</b>
<b>Monoclonal Antibodies .....</b>	<b>10</b>
<b>Cytokines.....</b>	<b>13</b>
<b>Recombinant Enzymes.....</b>	<b>14</b>
<b>Antihemophilia Factors.....</b>	<b>15</b>
<b>Other Recombinant Enzymes.....</b>	<b>15</b>
<b>Recombinant Protein Hormones .....</b>	<b>18</b>
<b>Insulins .....</b>	<b>18</b>
<b>Other Recombinant Protein Hormones.....</b>	<b>19</b>
<b>Recombinant Vaccines .....</b>	<b>21</b>
<b>CONCLUSION.....</b>	<b>22</b>

# INTRODUCTION

The Colombian health system is going through an unprecedented crisis. The majority of researchers agree that the exponential growth of recoveries to FOSYGA<sup>1</sup> for drugs and services not included in the POS<sup>2</sup>, particularly in the last four years, was one of the most important factors that exacerbated the financial crisis of the health sector in Colombia. The public policy of deregulation and liberalization at-all-costs, in both the prices of medicines and the overall system, seems to be most responsible for this situation. In this context, the role of biotech drug prices played a decisive role<sup>3</sup>.

A summary of these cost was graphically represented in an infographic released by the Colombian Medical Federation (Federación Médica Colombiana, FMC):

**Figura 1: The exponential growth of recoveries and deregulation of the price of medications**



In this infographic, it can be seen that the recoveries to FOSYGA totaled 4,244 million COP for FY 1997-2000 increased to COP 56,174 million in 2002 and finally totaled COP 2,236,120 million in 2010.

<sup>1</sup> FOSYGA Fondo de Solidaridad y Garantía, es el mecanismo central del financiamiento de la salud pública en Colombia

<sup>2</sup> POS Plan Obligatorio de Salud. Los beneficios no incluidos en este plan se prestan y luego se "recobran" al sistema.

<sup>3</sup> Ver FEDESARROLLO "[Pertinencia de incentivar la competencia en el mercado de medicamentos biotecnológicos..](#)" AR

These dates coincide with important public-health policy changes. In 2002, sensing the potential danger that recoveries had for the financial viability of the health system and the role their prices would play, former Minister of Labor and Health, Juan Luis Londono, sanctioned 32 laboratories and promoted the passage of 132 molecules to direct control system and more than 1,000 products to be freely regulated<sup>4</sup>. Upon his death in 2003, Londono was replaced by Diego Palacio Betancourt, who promoted deregulation, which resulted in an increase in recoveries from 113 million COP to 2,236,120 million (2.2 trillion) COP in 2003 and 2010, respectively, during his tenure as minister.

The infographic also allows the comparison of the problem in both sectors. The number of recoveries was growing, demanding drastic and efficient regulatory policies, while paradoxically, the National Drug Price Commission (Comisión Nacional de Precios de Medicamentos, CNPM)<sup>5</sup> reduced the control of the cancer drugs in January, 2004 and in April of 2006, was purported to set new price mechanisms of control, but in practice, completely freed price controls.

We can also see how the mechanism of recovery influences recoveries themselves. The blue bars represent recoveries through the Scientific Technical Committee (Comités Técnico Científicos, CTC), which had a price control mechanism controlled by Health Promoting Companies (Empresas Promotoras de Salud, EPS), while the red bars represent recoveries through litigation (Tutelas). These disputes over the right to health have allowed Colombia to become one of the countries in South America with the most voluminous and costly litigation.

The policy of severe deregulation and liberalization, coincided with regulatory gaps and an apparent weakness of inspection, monitoring and control mechanisms, giving rise to networks of actors, many of whom were corrupt, in the brokerage of pharmaceutical care, generating a verifiable "recovery industry" which severely disfigured the financing of the health system.

Per the World Bank, the Colombian government covers about 83.36% of all costs associated with health in the country, compared to the 70% covered by the Canadian government.<sup>6</sup> These results do not fully reflect the situation because, in addition to differences in institutional strength, Canada never implemented the deregulation policies that were observed in Colombia and the pharmaceutical market in Canada, in particular, is governed by rules that defend public health. Monopolies in the field of biotech drugs are a global problem, but very few countries were abused in such a way as was observed in Colombia.

In late 2009, the outgoing government recognized the magnitude of the crisis in the health sector and issued a decree of "social emergency" to restructure the entire system, [decree 4975](#). This consisted of 14 separate decrees, 11 of which sought to "free up more resources for health" and 3 sought to "contain costs and rationalize the use of resources"<sup>7</sup>.

These measures generated the mobilization of civil society because it restricted their fundamental rights and finally, in April 2010, the Constitutional Court declared the social emergency unconstitutional, causing the fall of the rules issued there-under<sup>8</sup>.

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<sup>4</sup> Ver detalles en [http://www.med-informatica.net/BIS/BisBcm13de2012\\_26mar01abr12.htm](http://www.med-informatica.net/BIS/BisBcm13de2012_26mar01abr12.htm)

<sup>5</sup> Comisión de alto nivel integrada por un representante de la Presidencia de la República, el Ministro de Salud (hoy Salud y Protección Social) y el Ministro de Desarrollo (hoy Comercio, Industria y Turismo).

<sup>6</sup> [http://www.cmaj.ca/site/earlyreleases/29feb12\\_health-in-colombia-a-system-in-crisis.xhtml](http://www.cmaj.ca/site/earlyreleases/29feb12_health-in-colombia-a-system-in-crisis.xhtml) ver link AR

<sup>7</sup> Ver detalles en [http://www.med-informatica.net/BIS/BisBcm04de2010\\_18a24ene10.htm](http://www.med-informatica.net/BIS/BisBcm04de2010_18a24ene10.htm)

<sup>8</sup> Ver [Noticia y video en El Espectador](#).

After the collapse of the social emergency, the outgoing government presented to congress a "mini-reform" tax to preserve their financial measures. In contrast, the measures that aimed to contain spending and rationalize the use of resources, were weak, inconsistent, contradictory and failed, as claimed by the FMC<sup>9</sup> and other analysts<sup>10</sup>.

The change in government brought about a new Ministry of Social Protection that understood the important role biotech drugs and monopolies played in the exponential growth of recoveries and issued a series of resolutions, which set maximum recovery values (Valores Máximos de Recobro, VMR) for 135 molecules that played large roles in the total cost of recoveries.<sup>11</sup>

The FMC recognized some value in the setting of the VMR but argued that the adjustments were insufficient, especially because biotech drugs, still had a VMR set higher than international prices, had such a tremendous impact in the total cost.<sup>12</sup>

To gain a greater understanding of the impact this has on Colombia, we conducted this analysis comparing the prices of 48 biotech drugs in Colombia with the price for the same products in Spain (same medications means the same active ingredient, dosage, strength, presentation and, in virtually all cases, the same name and manufacturer). This simple empirical approach to this issue, based on inside information that guides the FMC, both in relationship to a database of information from the pharmaceutical companies that is periodically sent to the Drug Information System of Ministry of Social Protection (Sistema de Información de Medicamentos del Ministerio de la Protección Social, SISMED),<sup>13</sup> and in relationship to a database that the FMC keeps about recoveries, the same database that has been obtained through tutelas and an ongoing legal battle.<sup>14</sup>

The information provided to SISMED has inconsistencies mentioned in other studies, but is the only official information and is validated in three aspects useful for this study; it reports the Unique Drug Codes (Código Unico del Medicamento, CUM), which together with the name registered on INVIMA<sup>15</sup> and the sales and price data reported by the pharmaceutical industry, are sufficient for this report. For this report, the inconsistencies in data reported by wholesalers, purchasing the system and others are not relevant. We do not include any data from 2007, because it has serious inconsistencies.

Our choice of Spain as a reference country also contradicts the comparisons in other studies, but has do deal with the availability of comparable data and the importance of comparing Colombia, a developing country, with a member of the European Union. Specifically, to address whether the case in Colombia is an example of big pharma adjusting to market dynamics or whether they have shown corporate social responsibility with their pricing scheme.

The recovery data from FOSYGA was analyzed by the Medication Monitoring Bureau of the FMC and was rejected five times, due to serious inconsistencies in the data, by the administrator of the FOSYGA trustee consortium (Fidofosyga) and the Ministry of Health and Social Protection.

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<sup>9</sup> Ver [Boletín FMC sobre este tema](#).

<sup>10</sup> <http://thepharmaceutical-news.com/effects-of-drug-price-deregulation-colombia>

<sup>11</sup> Ver [Resolución 4316 de 2011](#) que ratificó o rectificó Resoluciones 3470, 3026, 1020 y 05 de 2011

<sup>12</sup> Ver [Boletín FMC sobre este tema](#).

<sup>13</sup> SISMED es el sistema de información de precios de medicamentos del Ministerio de Salud y Protección Social. [Ver reportes](#).

<sup>14</sup> Ver resumen en el [Informe de la FMC](#) para la última Audiencia de Seguimiento de la Sentencia T-760

<sup>15</sup> Instituto Nacional de Vigilancia de Medicamentos y Alimentos INVIMA, agencia reguladora similar a FDA y EMA. [Ver página web](#).



According to the FMC, both fidofosyga and the Ministry of Health and Social Protection recognized that the magnetic records of recoveries for the years 2005 to 2010 do not match the physical documentation. This lack of reliable data on recoveries (which, through the years 2007 to 2010, the National Superintendant of Health estimated to be greater than COP 5.8 billion while recoveries in 2007 reached COP 1.0 trillion according to the Ministry and COP 557 billion according to Supersalud) was dubbed the “computer catastrophe” and called into question the validity of information on this topic.<sup>16</sup> As a result, this report includes a couple of infographics to help imagine the colossal magnitude of the cost attributed to pharmaceuticals. The FMC will deliver a special report on this issue when the current trustee "Consortium SAYP" delivers the information that they have promised since December 2011.

Returning to the issue of quantifying the total amount that the government of Colombia overpaid for biotech drugs, through the years 2008 to 2011, between 23 and 25 drugs were found to be more expensive in Colombia by year, during the four year period. During that same time period, 13 to 17 drugs were more expensive in Spain than in Colombia each year.<sup>17</sup>

**Chart 1. Number of medications, relative price differences by group.**

	Colombia > Spain	Spain > Colombia	No Comparison	Total
<b>TOTALS</b>				
2008	25	18	5	48
2009	29	15	4	48
2010	30	17	1	48
2011	28	19	1	48
<b>MONOCLONAL ANTIBODIES</b>				
2008	9	3	3	15
2009	11	1	3	15
2010	12	3	0	15
2011	8	7	0	15
<b>CYTOKINES</b>				
2008	5	1	0	6
2009	5	1	0	6
2010	4	2	0	6
2011	3	2	1	6
<b>ENZYMES</b>				
2008	6	7	1	14
2009	8	6	0	14
2010	7	6	1	14
2011	11	3	0	14
<b>HORMONE PROTEINS</b>				
2008	5	5	1	11
2009	5	5	1	11
2010	6	5	0	11
2011	5	6	0	11
<b>VACCINES</b>				
2008	0	2	0	2
2009	0	2	0	2
2010	1	1	0	2
2011	1	1	0	2

<sup>16</sup> Ver [Ultimo Informe de la FMC](#) sobre este tema.

<sup>17</sup> Ver [Respuesta del Consorcio SAYP a derecho de petición de la Federación Médica Colombiana](#).



In the cases where they could be analyzed, the costs of biotech drugs in Colombia amounted to COP 1.8 trillion or US\$ 1.5 billion in the years 2008 to 2011. Of the total cost, when comparing to reference price in Spain in 2011, Colombia was overcharged approximately COP 688,430,523,790 in the four-year period. It is shocking that, for the same biotech drugs, from the same pharmaceutical companies, the costs were significantly more in a developing country than in a country in the European Union.

In international forums, large pharmaceutical companies argue that they aid and abet developing nations by applying differential pricing to their products, that is, assigning higher prices in more developed countries and lower prices in less developed countries. Of the medications studied in this analysis where the price was more in Spain than in Colombia (which meets the definition of differential pricing described above or where the Spanish health system failed to regulate their prices) the total that Spain paid greater than Colombia was COP 142 billion.

The FMC has strongly argued that, in Colombia, the policy of adjusting the cost of medications to the international prices should be applied as soon as possible, both to eliminate being overcharged, which violates fundamental humanistic principles, and to abide by the practice of differential pricing of pharmaceuticals, which should have Colombia paying less than the average, worldwide price. For this reason, this report provides and estimated savings that implementing this policy will provide in each grouping of drugs.

## 1. Methods

Prices for this analysis were obtained from two databases that handle government reference pricing. Prices from Colombia were obtained from the SISMED VMI-CFN (Vademécum Med-Informática – Catálogo Farmacéutico Nacional) which validates and publishes data on the sales and prices of pharmaceuticals reported by the drug companies to SISMED. Prices from Spain were obtained from the General Council of Official Colleges of Pharmaceuticals (Consejo General de Colegios Oficiales de Farmacéuticos, CGCOF) 2011 publication of retail prices (Precios de Venta al Público, PVP) which is published on behalf of the Spanish Agency for Medicines and Medical Devices (Agencia Española de Medicamentos y Dispositivos Médicos, AEMPS) via their website (<https://botplusweb.portalfarma.com>). These PVP are considered useful for comparison, although in Spain there are additional mechanisms to reduce costs, such as the agreements adopted by the Interministerial Commission on Medication Prices, an organization similar to SISMED.

Spanish prices were multiplied by the conversion rate of 2571.32 COP/Euro, which was obtained on March 24, 2012. The sales data and prices in Colombia are at current values, ie not deflated.

To simplify the study, the products were selected and grouped according to the report "Overview of Biopharmaceuticals in Spain" by CGCOF and published in *Pharmacological Point No. 56*, on February 28<sup>th</sup>, 2011. The selection includes major biotech drugs and excluded products not available in Colombia or those drugs where no equivalent exists.

## 2. Comparison by group

The report "Overview of biopharmaceuticals in Spain" from CGCOF classifies biopharmaceuticals into six groups: monoclonal antibodies, cytokines, growth factors, hematopoietic factors, proteins and peptides and vaccines. To facilitate comparison, the available drugs in Colombia were grouped similarly and this report will provide data based on five (5) groups: Monoclonal Antibodies, Cytokines, recombinant enzymes, recombinant protein hormones and recombinant vaccines.

## 2.1. Monoclonal Antibodies

A total of 15 monoclonal antibodies were analyzed during the period 2008 to 2011. Between 8 and 12 of them were found more expensive in Colombia than in Spain. Between 3 and 7 were more expensive in Spain than in Colombia and between 0 and 3 could not be analyzed [Table 1].

The medications included in the monoclonal antibody group represented a total cost of 1.4 trillion over 4 years, as reported to SISMED. This group also represents highest cost for failing to implement international equivalents to the PVP in Spain and was estimated to be COP 334 billion. The medications where the cost in Spain was greater than that in Colombia totaled COP 29 billion. If price adjustment policies lowered Colombian prices to that of the international prices, it would have generated savings of at least an additional COP 334 billion [Table 2].

**Tabla 2: Monoclonal Antibodies – Sales and the impact of different prices (IDP)**

	2008	2009	2010	2011	Total	% del Total
<b>Sales in Colombia</b>	285,919,050,832	337,787,409,660	474,601,142,926	371,618,104,446	1,469,925,707,864	
<b>Units Sold</b>	98,479	112,400	175,505	172,826		
<b>OC* Colombia &gt; España</b>	78,657,523,001	100,639,803,325	116,696,775,506	38,143,719,282	334,137,821,113	49.10%
<b>OC* España &gt; Colombia</b>	-369,221,949	-6,570,472,075	-70,401,562	-22,326,340,401	-29,336,435,988	12.11%

\* OC = Overcharge

Recently the FMC, [accused the former minister](#), Diego Palacio B., for allegedly favoring the multinational Roche, citing the case of several high-impact products. Included are three monoclonal antibodies; Rituximab (Mabthera ®), Trastuzumab (Herceptin ®) and Bevacizumab (Avastin ®), which SISMED reported to be COP 722 billion over 4 years. For failing to implement the Spanish PVP equivalent, Colombia paid a major price for these three medications, an estimated COP 235 billion. In only one year, 2011, was one of these medications less expensive in Colombia than in Spain. In 2011, Avastin® was less expensive in Colombia and resulted in a comparative savings of COP 5.6 billion [Table 3].

**Tabla 3: The three Roche Biologics - Mabthera, Herceptin, Avastin - Sales and the impact of different prices (IDP)**

	2008	2009	2010	2011	Total	% del Total
<b>Sales in Colombia</b>	125,407,652,288	178,212,476,083	248,835,794,806	170,177,251,586	722,633,174,763	
<b>Units Sold</b>	26,971	45,732	77,408	65,550		
<b>OC* Colombia &gt; España</b>	52,392,718,321	76,692,241,782	82,839,859,380	23,565,959,991	235,490,779,473	35.70%
<b>OC* España &gt; Colombia</b>	0	0	0	-5,627,232,915	-5,627,232,915	1.55%

\* OC = Overcharge

A more detailed analysis of sales reported for the drug (units sold and costs) and price differences between Colombia and Spain, effectively shows that the drugs mentioned by the FMC represent the major overcharge and that such overcharges were maintained or increased in the reports of 2010 and fell significantly in 2011. The decrease in sales of Bevacizumab (Avastin ®) in 2011 is significant, in both in units and costs, but it is unknown whether this is due to regulation of the price, or whether this is due to the FDA reversal of the cancer indication of the drug and INVIMA followed without accepting its ophthalmic indications [Table 4].

In Table 4, we can see that in 2011 only a few monoclonal antibodies, Adalimumab (Humira®) or palivizumab (Synagis®) and to a lesser extent Omalizumab (Xolair®) and Ranibizumab (Lucentis®), show an increase in units sold along with a reduction in the per unit cost of the medications. These four cases can be interpreted as actual effect of the VMR and the consequent change in their prices.

Etanercept (Enbrel®) and infliximab (Remicade®) and to a lesser extent Cetuximab (Erbix®), showed decreased price with a slightly marked decrease in unit sales. This could be interpreted as a result of price adjustment and additional factors that decreased consumption.

Two drugs, Abatacept (Orencia®) and Abciximab (ReoPro®), only had significant sales reported in 2011. As neither of these medications are new to the market, they would likely fall into a category of medications which were under-reported or for which there was a lack of reporting to SISMED. Of these two drugs, only one, Abatacept, had a set VMR.

Three other drugs, Ustekinumab (Stelara®), Alemtuzumab (MabCampath®), and basiliximab (Simulect®) had limited sales, limited data and no set VMR.

**Table 4: Detail of Monoclonal Antibodies – Sales and the impact of different prices (IDP)**

Medicamento	Año	SobrePrecio Anual	VentaUnidades	Valor Ventas	% of total AFBEC	% Valor SP/TA
<b>1. Rituximab (Mabthera) Con VMR</b>	2008	36,195,915,293	12,583	72,098,539,117	50.20%	25.15%
	2009	49,796,705,794	16,087	94,621,090,570	52.63%	26.70%
	2010	49,880,240,281	22,691	111,658,778,577	44.67%	23.33%
	2011	18,576,476,156	19,898	75,016,805,916	24.76%	13.63%
	<b>Total</b>	<b>154,449,337,524</b>	<b>71,259</b>	<b>353,395,214,180</b>	<b>43.70%</b>	<b>22.70%</b>
<b>Adalimumab (Humira) Con VMR</b>	2008	9,567,559,867	14,518	51,660,225,786	18.52%	6.65%
	2009	15,726,293,579	20,365	74,771,419,729	21.03%	8.43%
	2010	5,736,691,159	19,707	62,874,049,422	9.12%	2.68%
	2011	-9,107,578,431	24,373	61,558,115,635	-14.80%	-15.03%
	<b>Total</b>	<b>21,922,966,174</b>	<b>78,963</b>	<b>250,863,810,572</b>	<b>8.74%</b>	<b>3.22%</b>
<b>Trastuzumab (Herceptin) Con VMR</b>	2008	12,648,968,612	4,451	35,428,470,001	35.70%	8.79%
	2009	20,340,147,718	6,286	52,510,883,672	38.74%	10.90%
	2010	26,743,058,360	11,497	85,582,853,343	31.25%	12.51%
	2011	4,989,483,835	11,767	65,211,092,542	7.65%	3.66%
	<b>Total</b>	<b>64,721,658,525</b>	<b>34,001</b>	<b>238,733,299,558</b>	<b>27.11%</b>	<b>9.51%</b>
<b>Etanercept (Enbrel/Étanar) Con VMR</b>	2008	1,264,132,015	13,391	28,357,478,203	4.46%	0.88%
	2009	-6,570,472,075	24,203	50,718,249,177	-12.95%	-6.47%
	2010	1,162,259,262	23,850	58,455,004,373	1.99%	0.54%
	2011	-6,296,132,904	19,481	43,025,355,900	-14.63%	-10.39%
	<b>Total</b>	<b>-10,440,213,702</b>	<b>80,925</b>	<b>180,556,087,652</b>	<b>-5.78%</b>	<b>-4.31%</b>
<b>Infliximab (Remicade) Con VMR</b>	2008	10,633,635,882	24,074	48,757,813,578	21.81%	7.39%
	2009	103,593,729	123	298,379,550	34.72%	0.06%
	2010	16,304,187,476	31,053	65,480,480,987	24.90%	7.63%
	2011	1,805,720,563	14,747	25,159,431,973	7.18%	1.32%
	<b>Total</b>	<b>28,847,137,650</b>	<b>69,997</b>	<b>139,696,106,088</b>	<b>20.65%</b>	<b>4.24%</b>
<b>Bevacizumab (Avastin) Con VMR</b>	2008	3,547,834,416	9,937	17,880,643,170	19.84%	2.46%
	2009	6,555,388,270	23,359	31,080,501,841	21.09%	3.51%
	2010	6,216,560,739	43,220	51,594,162,886	12.05%	2.91%

	2011	-5,627,232,915	33,885	29,949,353,128	-18.79%	-9.29%
	<b>Total</b>	<b>10,692,550,509</b>	<b>110,401</b>	<b>130,504,661,025</b>	<b>8.19%</b>	<b>1.57%</b>
Palivizumab (Synagis) Con VMR	2008	2,710,060,279	7,349	16,181,566,335	16.75%	1.88%
	2009	4,052,214,132	8,763	20,555,593,890	19.71%	2.17%
	2010	3,523,674,157	8,627	19,814,310,047	17.78%	1.65%
	2011	-456,723,948	11,112	21,200,818,487	-2.15%	-0.75%
	<b>Total</b>	<b>9,829,224,620</b>	<b>35,851</b>	<b>77,752,288,759</b>	<b>12.64%</b>	<b>1.44%</b>
Cetuximab (Erbix) Con VMR	2008	1,950,473,327	7,514	6,737,032,716	28.95%	1.36%
	2009	3,935,469,799	12,980	12,728,877,546	30.92%	2.11%
	2010	2,817,174,149	10,010	9,359,357,398	30.10%	1.32%
	2011	1,491,142,850	7,492	6,263,687,825	23.81%	1.09%
	<b>Total</b>	<b>10,194,260,124</b>	<b>37,996</b>	<b>35,088,955,485</b>	<b>29.05%</b>	<b>1.50%</b>
Abatacept (Orencia) Con VMR	2008	0	0	0	Unknown	Unknown
	2009	0	0	0	Unknown	Unknown
	2010	49,679,045	75	127,042,350	39.10%	0.02%
	2011	6,809,389,185	21,527	29,014,720,695	23.47%	5.00%
	<b>Total</b>	<b>6,859,068,230</b>	<b>21,602</b>	<b>29,141,763,045</b>	<b>23.54%</b>	<b>1.01%</b>
Ranibizumab (Lucentis) Con VMR	2008	-84,372,883	2,451	5,900,548,341	-1.43%	-0.28%
	2009	933,172	1	3,375,000	27.65%	0.00%
	2010	4,008,432,278	2,704	5,994,249,163	66.87%	1.87%
	2011	3,851,628,404	3,400	5,938,170,708	64.86%	2.83%
	<b>Total</b>	<b>7,776,620,971</b>	<b>8,556</b>	<b>17,836,343,212</b>	<b>43.60%</b>	<b>1.14%</b>
Omalizumab (Xolair) Con VMR	2008	-125,855,742	1,655	1,733,770,323	-7.26%	-0.41%
	2009	1,658,153	6	8,400,000	19.74%	0.00%
	2010	-21,917,838	1,541	1,709,613,138	-1.28%	-0.04%
	2011	-776,763,773	3,476	3,129,012,784	-24.82%	-1.28%
	<b>Total</b>	<b>-922,879,200</b>	<b>6,678</b>	<b>6,580,796,245</b>	<b>-14.02%</b>	<b>-0.38%</b>
Ustekinumab (Stelara) Sin VMR	2008	0	0	0	Unknown	Unknown
	2009	0	0	0	Unknown	Unknown
	2010	-3,525,309	73	603,235,500	-0.58%	-0.01%
	2011	-22,407,442	464	3,834,264,000	-0.58%	-0.04%
	<b>Total</b>	<b>-25,932,750</b>	<b>537</b>	<b>4,437,499,500</b>	<b>-0.58%</b>	<b>-0.01%</b>
Alemtuzumab (Mabcampath) Sin VMR	2008	0	0	0	Unknown	Unknown
	2009	78,391,747	73	318,421,255	24.62%	0.04%
	2010	222,829,195	231	982,374,624	22.68%	0.10%
	2011	202,941,268	201	863,844,434	23.49%	0.15%
	<b>Total</b>	<b>504,162,210</b>	<b>505</b>	<b>2,164,640,313</b>	<b>23.29%</b>	<b>0.07%</b>
Abciximab (Reopro) Sin VMR	2008	138,943,311	303	381,363,375	36.43%	0.10%
	2009	49,007,232	154	172,217,430	28.46%	0.03%
	2010	31,989,405	160	160,000,000	19.99%	0.01%
	2011	416,937,020	901	1,137,796,683	36.64%	0.31%
	<b>Total</b>	<b>636,876,969</b>	<b>1,518</b>	<b>1,851,377,488</b>	<b>34.40%</b>	<b>0.09%</b>
Basiliximab (Simulect) Sin VMR	2008	-158,993,324	253	801,599,887	-19.83%	-0.52%
	2009	0	0	0	Unknown	Unknown
	2010	-44,958,415	66	205,631,118	-21.86%	-0.09%
	2011	-39,500,990	102	315,633,737	-12.51%	-0.07%
	<b>Total</b>	<b>-243,452,730</b>	<b>421</b>	<b>1,322,864,742</b>	<b>-18.40%</b>	<b>-0.10%</b>

## 2.2. Cytokines

A total of 6 cytokines were analyzed during the period 2008 to 2011. Depending upon the year, between 3 and 5 of them were found more expensive in Colombia than in Spain and between 1 and 2 were more expensive in Spain than in Colombia and only one could not be analyzed [Table 1].

For the medications analyzed in this report in the cytokine group, SISMED reported total sales of 355 billion over the four-year period. The savings that could have been generated, had Colombia implemented price controls comparable to the price in Spain, would have generated an estimated COP 93 billion. In the cases where prices in Spain were higher than in Colombia, savings totaled COP 27 billion [Table 5].

**Table 5: Cytokines – Sales and the impact of different prices (IDP)**

	2008	2009	2010	2011	Total	% del Total
<b>Sales in Colombia</b>	73,729,755,216	100,722,322,048	117,707,025,718	63,453,379,797	355,612,482,779	
<b>Units Sold</b>	40,452	50,664	62,152	46,532		
<b>OC* Colombia &gt; España</b>	21,905,664,938	30,617,140,994	32,325,923,634	8,653,258,348	93,501,987,914	13.74%
<b>OC* España &gt; Colombia</b>	-3,223,359,606	-4,552,204,805	-8,581,774,940	-10,897,920,728	-27,255,260,078	11.25%

\* OC = Overcharge

The cytokines analyzed exhibited interesting behavior once the VMR's were set in 2011. As can be seen in Table 6, none of the cytokines examined had increased sales while they all had per unit price decreases. All of the cytokines analyzed (listed in decreasing order of their cumulative sales from 2008 to 2010) Interferon beta-1b (Betaferon ®), Interferon beta-1a (Avonex ®), Interferon beta-1a (Rebif ®), Pegfilgrastim (Neulastim ®), Interferon alpha 2A (Pegasys ®) and Filgrastim (Neupogen ®) exhibited a fairly significant decrease in per unit costs in 2011. While the VMR most likely had direct impact on these costs, we interpret this as an effect of additional factors in the market that decreased consumption.

Of these medications, only Neulastim ® was less expensive in Colombia for the four years shown.

**Table 6: Detail of Cytokines – Sales and the impact of different prices (IDP)**

CITOCINAS		66,246,727,836				
Medicamento	Año	SobrePrecio Anual	VentaUnidades	Valor Ventas	% of total AFBEC	% Valor SP/TA
Interferon Beta 1B (Betaferon) Con VMR	2008	13,186,285,236	7,495	31,644,084,802	41.67%	9.16%
	2009	14,427,728,933	8,060	34,276,943,677	42.09%	7.74%
	2010	16,612,475,057	11,408	44,706,748,233	37.16%	7.77%
	2011	7,624,826,275	11,168	35,128,055,836	21.71%	5.59%
	<b>Total</b>	<b>51,851,315,501</b>	<b>38,131</b>	<b>145,755,832,548</b>	<b>35.57%</b>	<b>7.62%</b>
Interferon Beta 1A (Avonex) Con VMR	2008	2,694,762,734	4,863	14,161,232,574	19.03%	1.87%
	2009	7,474,587,844	8,683	27,948,237,365	26.74%	4.01%
	2010	6,541,114,159	6,756	22,471,089,532	29.11%	3.06%
	2011	1,206,089,601	4,040	10,732,007,379	11.24%	0.88%
	<b>Total</b>	<b>16,710,464,738</b>	<b>20,302</b>	<b>64,580,559,471</b>	<b>25.88%</b>	<b>2.46%</b>
Interferon Beta 1A (Rebif)	2008	3,395,957,597	2,340	11,049,680,826	30.73%	2.36%
	2009	5,416,815,324	3,246	16,033,903,188	33.78%	2.90%
	2010	6,035,480,637	3,552	17,653,440,000	34.19%	2.82%

<b>Con VMR</b>	<b>2011</b>	<b>608,613,614</b>	<b>2,040</b>	<b>6,654,963,570</b>	<b>9.15%</b>	<b>0.45%</b>
	<b>Total</b>	<b>15,456,867,172</b>	<b>11,178</b>	<b>51,391,987,584</b>	<b>30.08%</b>	<b>2.27%</b>
<b>Pegfilgrastim (Neulastim) Con VMR</b>	<b>2008</b>	<b>-3,223,359,606</b>	<b>4,017</b>	<b>5,833,961,715</b>	<b>-55.25%</b>	<b>-10.56%</b>
	<b>2009</b>	<b>-4,552,204,805</b>	<b>6,326</b>	<b>9,711,328,846</b>	<b>-46.88%</b>	<b>-4.48%</b>
	<b>2010</b>	<b>-7,972,164,105</b>	<b>11,730</b>	<b>18,476,025,861</b>	<b>-43.15%</b>	<b>-16.10%</b>
	<b>2011</b>	<b>-10,453,986,186</b>	<b>10,262</b>	<b>12,684,234,226</b>	<b>-82.42%</b>	<b>-17.26%</b>
	<b>Total</b>	<b>-26,201,714,701</b>	<b>32,335</b>	<b>46,705,550,648</b>	<b>-56.10%</b>	<b>-10.82%</b>
<b>Interferon Alfa 2A (Pegasy) Con VMR</b>	<b>2008</b>	<b>2,518,817,580</b>	<b>7,222</b>	<b>6,438,242,510</b>	<b>39.12%</b>	<b>1.75%</b>
	<b>2009</b>	<b>3,169,334,606</b>	<b>7,953</b>	<b>7,484,315,900</b>	<b>42.35%</b>	<b>1.70%</b>
	<b>2010</b>	<b>3,136,853,780</b>	<b>10,538</b>	<b>8,859,795,282</b>	<b>35.41%</b>	<b>1.47%</b>
	<b>2011</b>	<b>419,818,459</b>	<b>6,899</b>	<b>4,128,943,570</b>	<b>10.17%</b>	<b>0.31%</b>
	<b>Total</b>	<b>9,244,824,424</b>	<b>32,612</b>	<b>26,911,297,262</b>	<b>34.35%</b>	<b>1.36%</b>
<b>Filgrastim (Neupogen) Con VMR</b>	<b>2008</b>	<b>109,841,792</b>	<b>14,515</b>	<b>4,602,552,789</b>	<b>2.39%</b>	<b>0.08%</b>
	<b>2009</b>	<b>128,674,286</b>	<b>16,396</b>	<b>5,267,593,072</b>	<b>2.44%</b>	<b>0.07%</b>
	<b>2010</b>	<b>-609,610,835</b>	<b>18,168</b>	<b>5,539,926,810</b>	<b>-11.00%</b>	<b>-1.23%</b>
	<b>2011</b>	<b>-443,934,542</b>	<b>16,163</b>	<b>4,857,182,595</b>	<b>-9.14%</b>	<b>-0.73%</b>
	<b>Total</b>	<b>-815,029,298</b>	<b>65,242</b>	<b>20,267,255,266</b>	<b>-4.02%</b>	<b>-0.34%</b>

### 2.3. Recombinant Enzymes

A total of 15 recombinant enzymes were analyzed during the period 2008 to 2011. Between 6 and 11 of them were found more expensive in Colombia than in Spain per year. Between 4 and 8 were determined to be more expensive in Spain than in Colombia and only one could not be analyzed [Table 1].

The group of recombinant enzymes included in this analysis totaled sales of COP 595 billion reported to SISMED over 4 years. The cost that Colombia paid for not implementing the international price in this case was estimated at COP 227 billion. For the medications that were more expensive in Spain, they overpaid (when compared to Colombia) COP 83,145,550,600 [Table 7].

**Tabla 7: Recombinant Enzymes – Sales and the impact of different prices (IDP)**

	<b>2008</b>	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>Total</b>	<b>% del Total</b>
<b>Sales in Colombia</b>	<b>105,470,174,363</b>	<b>145,770,075,458</b>	<b>181,978,495,502</b>	<b>162,320,813,081</b>	<b>595,539,558,404</b>	
<b>Units Sold</b>	<b>34,979,693</b>	<b>48,139,750</b>	<b>66,466,345</b>	<b>19,389,219</b>		
<b>OC* Colombia &gt; España</b>	<b>40,663,706,059</b>	<b>51,578,675,606</b>	<b>53,300,159,858</b>	<b>81,872,124,740</b>	<b>227,414,666,262</b>	<b>33.42%</b>
<b>OC* España &gt; Colombia</b>	<b>-16,965,031,712</b>	<b>-25,230,340,935</b>	<b>-32,633,600,119</b>	<b>-8,316,577,834</b>	<b>-83,145,550,600</b>	<b>34.33%</b>

\* OC = Overcharge

This grouping can be further broken down into two subcategories: Hemophilia factors and other recombinant factors.

#### 2.3.1. Antihemophilia Factors

The medications that comprise the subcategory of hemophilia factors in this report had total sales amounting to COP 536 billion as reported to SISMED over the 4 years. The amount overpaid for these medications in Colombia totaled COP 205 billion, which could have been saved, had the government set prices equivalent to those of the international prices. In cases where the price was higher in Spain, they overpaid by COP 81 billion when compared to Colombia [Table 8].



**Table 8: Antihemophilia Factors– Sales and the impact of different prices (IDP)**

	2008	2009	2010	2011	Total	% del Total
<b>Sales in Colombia</b>	95,372,151,016	132,886,813,491	164,292,227,287	144,082,812,271	536,634,004,065	
<b>Units Sold</b>	34,968,654	47,921,693	65,864,641	18,600,163		
<b>OC* Colombia &gt; España</b>	36,569,155,676	46,442,330,984	45,888,869,639	76,138,860,516	205,039,216,815	30.13%
<b>OC* España &gt; Colombia</b>	-16,743,342,185	-25,130,837,466	-32,482,805,145	-6,989,748,634	-81,346,733,431	33.59%

\* OC = Overcharge

### 2.3.2. Other recombinant enzymes

The other recombinant enzymes included in this analysis, those that are not hemophilia factors, had sales of COP 58 billion reported to SISMED over the four years. For these enzymes, Colombia could have saved an estimated COP 22 billion if they had lowered their prices to those in Spain. The medications that were more expensive in Spain totaled COP 1.8 billion over the four year period [Table 9].

**Tabla 9: Other Recombinant Enzymes – Sales and the impact of different prices (IDP)**

	2008	2009	2010	2011	Total	% del Total
<b>Sales in Colombia</b>	10,098,023,347	12,883,261,967	17,686,268,215	18,238,000,810	58,905,554,339	
<b>Units Sold</b>	11,039	218,057	601,704	789,056		
<b>OC* Colombia &gt; España</b>	4,094,550,383	5,136,344,622	7,411,290,219	5,733,264,224	22,375,449,448	3.29%
<b>OC* España &gt; Colombia</b>	-221,689,526	-99,503,469	-150,794,974	-1,326,829,200	-1,798,817,169	0.74%

\*OC = Overcharge

Table 10 shows that the only hemophilia factor to have a VMR set, Recombinant Factor VIIa (NovoSeven®), had a reduction in the per unit price and also had an increase in sales of the drug. This medication though, makes up a small percentage of the total market and can be considered a VMR of less significant effect.

Factor VIII coagulant anti-inhibitor complex (FEIBA) did not have a VMR set and, in 2011, had the highest premium for this subgroup.

NovoSeven® and FEIBA have the highest cumulative sales (COP 140 billion and COP 141 billion, respectively) and the highest cost over Spain for the subgroup (COP 95 billion and 85 billion, respectively)

For Drotecogina (Xigris®) the VMR appears to have been counterproductive because, the cost per unit of the drug greatly increased and utilization of the drug decreased.

It appears as if there is no uniformity in the reporting of sales and prices to SISMED. In some instances the data is reported in sales per unit, in others it is reported as sales per package. This points to a greater systemic error in the reporting system that decreases its value for analysis of this report.

In table 10, we can also see that the other recombinant enzymes contribute a seemingly insignificant in their sales volume. The meager sales are a direct result of the current sub-registration regulations in Colombia. Indeed, this corresponds to data released by the laboratories, which indicate that these products can be imported directly by other actors in the system such as Health Promoting Companies (Empresas Promotoras de Salud, EPS) and departmental governments, among others. Unlike the hemophilia drugs, the other recombinant enzymes included in this study, except for Alteplase (Actilyse®), had a VMR set in 2011 however, this seemed to only affect be effective in the case of Dornase Alfa (Pulmozyme®).



**Table 9: Detail of Antihemophilia Factors and other Recombinant Enzymes – Sales and the impact of different prices (IDP)**

Medicamento	Año	SobrePrecio Anual	VentaUnidades	Valor Ventas	% of total FBEC	% Valor SP/TA
Factor VIIa Rec (Novoseven) Con VMR	2008	27,062,574,748	3,931	38,425,239,191	70.43%	18.80%
	2009	29,096,571,999	4,074	40,493,958,853	71.85%	15.60%
	2010	21,822,314,274	2,428	29,257,486,720	74.59%	10.21%
	2011	17,245,288,078	5,561	31,919,933,584	54.03%	12.65%
	<b>Total</b>	<b>95,226,749,099</b>	<b>15,994</b>	<b>140,096,618,348</b>	<b>67.97%</b>	<b>13.99%</b>
Factor VIII CCAI (Feiba) Sin VMR	2008	9,303,616,216	4,749,040	19,613,618,100	47.43%	6.46%
	2009	16,908,439,282	7,884,581	34,025,592,426	49.69%	9.07%
	2010	22,725,978,010	10,283,000	45,050,016,000	50.45%	10.63%
	2011	36,256,049,711	2,939,353	42,637,283,596	85.03%	26.60%
	<b>Total</b>	<b>85,194,083,220</b>	<b>25,855,974</b>	<b>141,326,510,122</b>	<b>60.28%</b>	<b>12.52%</b>
Factor VIII Rec. (Recombinate) Sin VMR	2008	-8,369,711,768	11,299,667	13,740,633,421	-60.91%	-27.42%
	2009	-16,941,555,706	21,257,865	24,522,178,362	-69.09%	-16.68%
	2010	-18,856,993,699	25,178,020	30,321,860,074	-62.19%	-38.09%
	2011	13,403,980,193	7,973,523	28,311,472,057	47.34%	9.84%
	<b>Total</b>	<b>-30,764,280,981</b>	<b>65,709,075</b>	<b>96,896,143,914</b>	<b>-31.75%</b>	<b>-12.70%</b>
Factor VIII (Hemofil) Sin VMR	2008	-4,529,610,287	13,586,242	11,206,754,085	-40.42%	-14.84%
	2009	-4,021,523,620	12,415,768	10,006,102,772	-40.19%	-3.96%
	2010	-6,411,578,738	22,623,928	18,746,846,221	-34.20%	-12.95%
	2011	6,295,967,749	5,189,516	12,043,291,642	52.28%	4.62%
	<b>Total</b>	<b>-8,666,744,896</b>	<b>53,815,454</b>	<b>52,002,994,720</b>	<b>-16.67%</b>	<b>-3.58%</b>
Factor VIII Rec. (Kogenate) Sin VMR	2008	-255,596,963	3,935	3,256,013,363	-7.85%	-0.84%
	2009	-1,488,835,532	13,469	13,340,371,839	-11.16%	-1.47%
	2010	-3,812,463,107	25,797	24,993,852,572	-15.25%	-7.70%
	2011	-5,822,117,195	24,282	19,679,162,659	-29.59%	-9.61%
	<b>Total</b>	<b>-11,379,012,797</b>	<b>67,483</b>	<b>61,269,400,433</b>	<b>-18.57%</b>	<b>-4.70%</b>
Factor IX (Immunine) Sin VMR	2008	-1,580,215,687	5,320,868	8,164,542,592	-19.35%	-5.18%
	2009	-2,584,031,710	6,343,980	9,034,477,080	-28.60%	-2.54%
	2010	-2,864,643,037	7,744,900	11,319,542,400	-25.31%	-5.79%
	2011	2,842,790,782	2,462,138	7,352,006,132	38.67%	2.09%
	<b>Total</b>	<b>-4,186,099,652</b>	<b>21,871,886</b>	<b>35,870,568,204</b>	<b>-11.67%</b>	<b>-1.73%</b>
Nonacog (Advate) Sin VMR	2008	0	0	0	Unknown	Unknown
	2009	35,675,029	205,000	535,404,000	6.66%	0.02%
	2010	-85,025,621	585,750	1,310,802,250	-6.49%	-0.17%
	2011	1,911,826,855	773,479	3,763,106,970	50.80%	1.40%
	<b>Total</b>	<b>1,862,476,263</b>	<b>1,564,229</b>	<b>5,609,313,220</b>	<b>33.20%</b>	<b>0.27%</b>
Factor VIII (Beriate) Sin VMR	2008	-1,928,977,678	3,433	45,610,356	-4229.25%	-6.32%
	2009	-94,890,898	969	462,457,137	-20.52%	-0.09%
	2010	-537,126,564	3,549	1,504,182,184	-35.71%	-1.08%
	2011	-1,164,724,491	5,295	1,880,846,042	-61.93%	-1.92%
	<b>Total</b>	<b>-3,725,719,630</b>	<b>13,246</b>	<b>3,893,095,719</b>	<b>-95.70%</b>	<b>-1.54%</b>
Fibrinógeno +	2008	202,964,712	1,411	916,304,909	22.15%	0.14%

Factor VIII (Beriplast) Sin VMR	2009	332,828,791	551	613,389,990	54.26%	0.18%
	2010	943,157,734	1,548	1,743,541,793	54.09%	0.44%
	2011	94,784,002	432	220,716,559	42.94%	0.07%
	<b>Total</b>	<b>1,573,735,239</b>	<b>3,942</b>	<b>3,493,953,251</b>	<b>45.04%</b>	<b>0.23%</b>
Factor VIII + fVwb ( Haemate) Con VMR	2008	-79,229,802	127	3,434,999	-2306.55%	-0.26%
	2009	104,490,912	436	388,285,032	26.91%	0.06%
	2010	397,419,620	1,471	1,354,899,323	29.33%	0.19%
	2011	-2,906,949	63	38,100,000	-7.63%	0.00%
	<b>Total</b>	<b>419,773,781</b>	<b>2,097</b>	<b>1,784,719,354</b>	<b>23.52%</b>	<b>0.06%</b>
Medicamento	Año	SobrePrecio Anual	VentaUnidades	Valor Ventas	% of total FBEC	% Valor SP/TA
Dornase Alfa (Pulmozyme) Con VMR	2008	3,504,338,733	7,823	6,322,471,136	55.43%	2.43%
	2009	4,046,688,051	10,068	7,673,552,046	52.74%	2.17%
	2010	5,776,635,865	12,919	10,430,534,947	55.38%	2.70%
	2011	1,084,071,193	11,183	5,112,599,208	21.20%	0.80%
	<b>Total</b>	<b>14,411,733,841</b>	<b>41,993</b>	<b>29,539,157,337</b>	<b>48.79%</b>	<b>2.12%</b>
Alteplasa (Actilyse) Sin VMR	2008	436,156,435	353	1,432,457,876	30.45%	0.30%
	2009	700,615,182	473	2,035,602,665	34.42%	0.38%
	2010	1,048,671,228	699	3,021,517,424	34.71%	0.49%
	2011	1,642,667,360	1,009	4,490,452,498	36.58%	1.21%
	<b>Total</b>	<b>3,828,110,206</b>	<b>2,534</b>	<b>10,980,030,463</b>	<b>34.86%</b>	<b>0.56%</b>
Drotecogina (Xigris) Con VMR	2008	-187,545,685	2,696	1,783,023,864	-10.52%	-0.61%
	2009	-88,411,508	2,240	1,548,856,960	-5.71%	-0.09%
	2010	-65,769,353	2,003	1,398,270,264	-4.70%	-0.13%
	2011	540,900,618	1,618	1,723,534,717	31.38%	0.40%
	<b>Total</b>	<b>199,174,072</b>	<b>8,557</b>	<b>6,453,685,805</b>	<b>3.09%</b>	<b>0.03%</b>
Tenecteplasa (Metalyse) Con VMR	2008	154,055,215	127	512,233,431	30.08%	0.11%
	2009	353,366,360	236	1,018,957,376	34.68%	0.19%
	2010	585,983,125	333	1,525,143,330	38.42%	0.27%
	2011	553,798,199	389	1,650,895,255	33.55%	0.41%
	<b>Total</b>	<b>1,647,202,899</b>	<b>1,085</b>	<b>4,707,229,392</b>	<b>34.99%</b>	<b>0.24%</b>
Laronidasa (Aldurazyme) Con VMR	2008	-34,143,841	40	47,837,040	-71.38%	-0.11%
	2009	-11,091,961	40	70,888,920	-15.65%	-0.01%
	2010	0	0	0	Unknown	Unknown
	2011	-1,326,829,200	1,378	1,497,412,161	-88.61%	-2.19%
	<b>Total</b>	<b>-1,372,065,002</b>	<b>1,458</b>	<b>1,616,138,121</b>	<b>-84.90%</b>	<b>-0.57%</b>

### 3.4. Recombinant Hormone Proteins

A total of 10 recombinant protein hormones were analyzed during the period 2008 to 2011. Between 4 and 6 of them were found more expensive in Colombia than in Spain. Between 4 and 5 were more expensive in Spain than in Colombia and only one could not be analyzed [Table 1].

Over the four years analyzed, recombinant proteins accounted for total sales of COP 195 billion as reported to SISMED. Once again, if Colombia had utilized price restrictions to equalize the cost to that of Spain, they could have saved COP 12 billion from 2008 through 2011. For the medications that Colombia saved on relative to Spain, the total savings was approximately 2.7 billion [Table 1].

**Tabla 11: Recombinant Protein Hormones – Sales and the impact of different prices (IDP)**

	2008	2009	2010	2011	Total	% del Total
<b>Sales in Colombia</b>	38,759,340,265	57,040,057,832	67,155,647,298	32,226,383,230	195,181,428,625	
<b>Units Sold</b>	43,969,337	1,590,945	1,490,817	1,545,764		
<b>OC* Colombia &gt; España</b>	2,704,310,251	3,687,428,015	4,607,003,214	1,171,217,419	12,169,958,899	1.79%
<b>OC* España &gt; Colombia</b>	-343,758,178	-375,053,277	-576,469,135	-1,398,927,302	-2,694,207,891	1.11%

\*OC = Overcharge

This grouping can further be broken down into two sub-groupings, insulin and other recombinant proteins.

### 3.4.1 Insulins

The subset of insulin netted total sales of COP 119 billion, as reported to SISMED, over the four years studied. For this subset, Colombia overpaid, as compared to the cost in Spain, by COP 6 billion. In contrast, in the cases where the costs were greater in Spain, they only overpaid by COP 1.0 billion [Table 12].

**Tabla 12: Recombinant Protein Hormones – Insulins – Sales and the impact of different prices (IDP)**

	2008	2009	2010	2011	Total	% del Total
<b>Sales in Colombia</b>	26,162,678,170	37,751,311,030	40,164,039,135	15,769,280,020	119,847,308,355	
<b>Units Sold</b>	43,922,085	1,515,128	1,360,724	1,432,663		
<b>OC* Colombia &gt; España</b>	1,487,615,883	2,048,669,927	2,221,000,874	750,904,631	6,508,191,314	0.96%
<b>OC* España &gt; Colombia</b>	-217,704,708	-338,625,240	-484,467,553	0	-1,040,797,500	0.43%

\* OC = Overcharge

### 3.4.2 Other Recombinant Hormone Proteins

The subset of other recombinant protein hormones, as reported to SISMED, netted total sales of COP 75 billion over the four years studied. Here, Colombia could have saved COP 5.6 billion if the had enacted VMRs with prices similar to those in Spain. When the drugs were more expensive in Spain, the total cost savings was COP 1.6 billion [Table 13].

**Table 13: Other Recombinant Protein Hormones – Sales and the impact of different prices (IDP)**

	2008	2009	2010	2011	Total	% del Total
<b>Sales in Colombia</b>	12,596,662,095	19,288,746,802	26,991,608,163	16,457,103,210	75,334,120,270	
<b>Units Sold</b>	47,252	75,817	130,093	113,101		
<b>OC* Colombia &gt; España</b>	1,216,694,368	1,638,758,088	2,386,002,340	420,312,788	5,661,767,585	0.83%
<b>OC* España &gt; Colombia</b>	-126,053,470	-36,428,037	-92,001,582	-1,398,927,302	-1,653,410,391	0.68%

\* OC = Overcharge

In table 14, we see that for the years 2010 and 2011, Insulin Glargine (Lantus ®) and N Human Insulin (Humulin ®) had the largest sales volumes and also minimal cost over the cost in Spain. Neither drug had a VMR set in 2011, however, that is no longer necessary because they were included in the Compulsory Health Plan (Plan Obligatorio de Salud, POS) by the Article 29 of CRES on 30 December 2011.

The drastic reduction in the sales of Lantus® and Glulisine (Apidra®) in 2011 most likely corresponds to a case of under-reporting, or possibly a lack of reporting, to SISMED by Sanofi-Aventis, the owner of both brands.

Insulin Lispro (Humalog ®) was the only insulin that had a VMR until others were included in the POS by Article 29 of CRES.

Insulin detemir (Levemir ®) had meager sales and low costs, which were of little significance to this study.

In table 14, we can also analyze the other recombinant protein hormones. Recombinant Somatropin (Genotropin ®) from Pfizer appears to have both decent sales and price in Colombia that is less than the price in Spain. The Somatropines, Genotropin® together with the other Somatropines (Saizen ® and Humatrope ®), largely dominated this subgroup and accumulated the most sales. In 2011, Genotropin® and Saizen® showed significant decreases in the number of units sold, but had a greater cost savings per unit sold, which can be attributed to the VMR.

The other recombinant protein hormones analyzed, Human Albumin (Flexbumin ®) and thyrotropin (Thyrogen ®), have insignificant sales and overcharges.

**Tabla 14: Detail of the Recombinant Protein Hormones in Colombia and the impact of different prices (IDP)**

Medicamento	Año	SobrePrecio Anual	VentaUnidades	Valor Ventas	% of total FBEC	% Valor SP/TA
Insulin Glargine (Lantus) Sin VMR	2008	323,384,950	42,950,352	9,903,963,400	3.27%	0.22%
	2009	821,780,352	213,523	19,498,537,587	4.21%	0.44%
	2010	1,336,134,680	282,636	25,733,298,057	5.19%	0.62%
	2011	39,197,198	1,027	173,902,379	22.54%	0.03%
	<b>Total</b>	<b>2,520,497,180</b>	<b>43,447,538</b>	<b>55,309,701,423</b>	<b>4.56%</b>	<b>0.37%</b>
Human Insulin N (Humulin) Sin VMR	2008	279,596,169	930,594	12,964,575,531	2.16%	0.19%
	2009	217,089,562	1,218,357	13,269,394,666	1.64%	0.12%
	2010	73,686,151	972,303	8,882,541,493	0.83%	0.03%
	2011	87,318,401	1,390,995	11,576,412,786	0.75%	0.06%
	<b>Total</b>	<b>657,690,284</b>	<b>4,512,249</b>	<b>46,692,924,476</b>	<b>1.41%</b>	<b>0.10%</b>
Insulin Lispro (Humalog) Con VMR	2008	884,634,764	29,864	2,603,826,001	33.97%	0.61%
	2009	1,009,800,013	33,750	3,084,783,179	32.73%	0.54%
	2010	810,858,381	28,838	2,625,860,344	30.88%	0.38%
	2011	578,563,372	35,501	2,956,490,693	19.57%	0.42%
	<b>Total</b>	<b>3,283,856,529</b>	<b>127,953</b>	<b>11,270,960,217</b>	<b>29.14%</b>	<b>0.48%</b>
Insulin Glulisine (Apidra) Sin VMR	2008	-217,704,708	11,275	690,313,238	-31.54%	-0.71%
	2009	-338,625,240	49,498	1,898,595,598	-17.84%	-0.33%
	2010	-484,467,553	76,936	2,921,573,399	-16.58%	-0.98%
	2011	2,287,949	174	16,300,820	14.04%	0.00%
	<b>Total</b>	<b>-1,038,509,551</b>	<b>137,883</b>	<b>5,526,783,055</b>	<b>-18.79%</b>	<b>-0.43%</b>
Insulin Detemir (Levemir) Sin VMR	2008	0	0	0	Unknown	Unknown
	2009	0	0	0	Unknown	Unknown
	2010	321,662	11	765,842	42.00%	0.00%
	2011	43,537,711	4,966	1,046,173,341	4.16%	0.03%
	<b>Total</b>	<b>43,859,373</b>	<b>4,977</b>	<b>1,046,939,183</b>	<b>4.19%</b>	<b>0.01%</b>

Medicamento	Año	SobrePrecio Anual	VentaUnidades	Valor Ventas	% of total FBEC	% Valor SP/TA
Somatropin (Genotropin) Con VMR	2008	3.478.498.742	81	3.510.834.300	99,08%	2,42%
	2009	-7.632.437.264	52.284	11.769.123.987	-64,85%	-7,52%
	2010	-19.924.265.772	114.152	44.504.923.644	-44,77%	-40,24%
	2011	-17.737.189.894	75.959	25.451.083.927	-69,69%	-29,28%
	Total	-41.815.394.188	242.476	85.235.965.858	-49,06%	-17,27%
Somatropin (Saizen) Con VMR	2008	1,064,967,961	17,041	9,535,984,944	11.17%	0.74%
	2009	1,586,591,498	26,512	14,767,422,608	10.74%	0.85%
	2010	1,958,134,948	32,009	17,872,853,213	10.96%	0.92%
	2011	-1,129,790,068	18,548	8,091,621,196	-13.96%	-1.86%
	Total	3,479,904,340	94,110	50,267,881,961	6.92%	0.51%
Human Albumin (Flexbumin) Sin VMR	2008	-77,769,747	29,378	2,247,642,084	-3.46%	-0.25%
	2009	35,463,704	48,486	3,873,366,830	0.92%	0.02%
	2010	-92,001,582	97,360	7,614,516,761	-1.21%	-0.19%
	2011	-263,213,475	93,945	7,172,990,980	-3.67%	-0.43%
	Total	-397,521,100	269,169	20,908,516,655	-1.90%	-0.16%
Thyrotropin (Thyrogen) Con VMR	2008	151,726,407	174	593,180,070	25.58%	0.11%
	2009	16,702,886	157	415,026,019	4.02%	0.01%
	2010	411,771,792	367	1,342,883,828	30.66%	0.19%
	2011	420,312,788	318	1,080,417,482	38.90%	0.31%
	Total	1,000,513,873	1,016	3,431,507,399	29.16%	0.15%
Somatropin Humatrope Con VMR	2008	-48,283,723	659	219,854,997	-21.96%	-0.16%
	2009	-36,428,037	662	232,931,345	-15.64%	-0.04%
	2010	16,095,601	357	161,354,361	9.98%	0.01%
	2011	-5,923,759	290	112,073,553	-5.29%	-0.01%
	Total	-74,539,919	1,968	726,214,256	-10.26%	-0.03%

### 3.5. Recombinant Vaccines

The sales for recombinant vaccines totaled COP 166 billion for the four years analyzed, as reported to SISMED. In total, Colombia overpaid for these medications by an estimated 13 billion, when compared to the prices in Spain. When the costs were greater in Spain, Colombia saved an estimated COP 99 billion [Table 15].

**Tabla 15: Vacunas recombinantes - Ventas en Colombia e impacto diferencia precios (IDP)**

	2008	2009	2010	2011	Total	% del Total
Sales in Colombia	25,945,598,270	59,258,139,104	53,582,102,772	27,375,349,243	166,161,189,389	
Units Sold	176,124	623,330	302,425	165,925		
OC* Colombia > España	0	0	6,869,863,794	6,445,584,766	13,315,448,561	1.96%
OC* España > Colombia	-9,618,068,728	-64,827,461,855	-7,645,819,006	-17,638,869,790	-99,730,219,379	41.18%

\*OC = Overcharge

In table 16 we analyzed only the pneumococcal (Prevenar ®) and anti-HPV (Cervarix ®) vaccines. Both the total units sold and the cost per unit are distorted by the direct purchases of the vaccine by the institutions responsible for the vaccination programs in Colombia.

**Table 16: Vacunas Recombinantes**

Medicamento	Año	SobrePrecio Anual	VentaUnidades	Valor Ventas	% of total FBEC	% Valor SP/TA
Antipneumococcus (Prevenar) Sin VMF	2008	-6,229,014,197	144,109	20,380,206,715	-30.56%	-20.41%
	2009	-61,409,269,289	598,391	55,701,009,760	-110.25%	-60.47%
	2010	6,869,863,794	255,740	48,170,345,157	14.26%	3.21%
	2011	6,445,584,766	72,873	18,988,008,906	33.95%	4.73%
	<b>Total</b>	<b>-54,322,834,926</b>	<b>1,071,113</b>	<b>143,239,570,538</b>	<b>-37.92%</b>	<b>-22.43%</b>
Anti-HPV (Cervarix) Sin VMR	2008	-3,389,054,531	32,015	5,565,391,555	-60.90%	-11.10%
	2009	-3,418,192,566	24,939	3,557,129,344	-96.09%	-3.37%
	2010	-7,645,819,006	46,685	5,411,757,615	-141.28%	-15.44%
	2011	-17,638,869,790	93,052	8,387,340,337	-210.30%	-29.12%
	<b>Total</b>	<b>-32,091,935,893</b>	<b>196,691</b>	<b>22,921,618,851</b>	<b>-140.01%</b>	<b>-13.25%</b>

### 3. Conclusion:

The analysis performed on the sales data that were reported to SISMED of the Ministry of Health and Welfare, showed that a sample of 48 biotech drugs reported cumulative sales of **COP 2.7 trillion** (US \$1.5 billion) from 2008 to 2011.

When comparing the total costs of the medications in Colombia with the estimated costs of the same amounts of the same medications in Spain in 2011, our analysis showed that Colombia was overcharged **COP 668 billion**. This increased cost in Colombia was for products with the same active ingredient, form, strength, presentation, and often business name and owner.

These results are a direct contradiction to the claims laid out by the pharmaceutical companies, which claim to implement differential pricing in favor of less developed countries. Here, we effectively demonstrated that the cost of biotech drugs, which were mostly monopolies, had prices which were higher in Colombia than in Spain, a member of the European Union.

The results from this study confirm the claims laid out by other researchers, that biotech drugs, especially monopolies, had an enormous impact on the financial crisis that rocked the Colombian healthcare system. The major groups that affected this were found to be:

- ✓ Monoclonal antibodies, which reported sales of COP 1.4 trillion in the 4 years studied, with an estimated cost over Spain of COP 334.138 million from 8 to 12 drugs.
- ✓ Within the former group, three products of Roche, Rituximab (Mabthera®), Trastuzumab (Herceptin®) and Bevacizumab (Avastin®), which reported sales of COP 722.633 million over the 4 years, with a cost over Spain estimated to be COP 235 million.
- ✓ Recombinant Enzymes, which reported sales of COP 595 million in the 4 years with an estimated cost over Spain of COP 227.415 million from 6 to 11 drugs.
- ✓ Cytokines, which reported sales of COP 356 million over 4 years, with an estimated cost over Spain of COP 94 million from 3 to 5 medications.

Using Table 2 above, we can analyze the evolution of the amount that Colombia was overcharged on monoclonal antibodies. In 2008, there was an overcharge of COP 78.7 billion, in 2009 it was COP 100.6 billion, in 2010 it further increased to COP 116.7 billion and finally dropped to COP 38.1 billion in 2011 (Total of COP 334.1 million). The three Roche monoclonal antibodies,



rituximab (Mabthera ®), Trastuzumab (Herceptin ®) and Bevacizumab (Avastin ®), constituted COP 52.4 billion, COP 76.7 billion, COP 82.8 billion and COP 23.6 billion of the overcharge for monoclonal antibodies for the years 2008 through 2011, respectively (COP 235.5 million in total).

Recombinant enzymes were the only group in this study to see an increased cost over Spain in the year 2011. The total overcharges were COP 40.6 billion in 2008, COP 51.6 billion in 2009, 53.3 billion in 2010 and then sharply increased to COP 81.872 billion in 2011 (COP 227.4 billion in total)

Colombia was over charged for cytokines by COP 21.9 billion in 2008, COP 30.6 billion in 2009, COP 32.3 billion in 2010 and dropped to 9.9 billion in 2011 (Totaling COP 93.5 billion)

The trend for recombinant protein hormones is as follows: in 2008 Colombia overpaid, when compared to Spain, by COP 2.7 billion, by COP 3.7 billion in 2009, by COP 4.6 billion in 2010 and finally by 1.2 billion in 2011.

From our analysis, we can see a noticeable reduction in the amount Colombia was overcharged in 2011, with the exception of recombinant enzymes, which trended the opposite way, mainly because of Recombinant Factor VIIa (NovoSeven ®) and Factor VIII coagulant anti-inhibitor complex (FEIBA). These drugs had extremely high cumulative sales (COP 140 billion and COP 141 billion, respectively) and also had high cumulative overcharges (COP 95.2 billion and 85.2 billion, respectively). Note that NovoSeven® was assigned a VMR that was higher than the price paid in Spain while FEIBA was not assigned a VMR.

Figure number 2 shows that after resolutions 05, 1020, 3026, 3470 and 4316 were enacted in 2011, that the estimated amount being overpaid by Colombia, which had grown from COP 143.9 billion in 2008 to COP 186.5 billion in 2009 and to COP 213.8 billion in 2010, decreased to COP 137.5 billion in 2011, when compared to Spain. This data indicates that the VMRs set for these products helped to decrease the growth of overcharges that are so drastically affecting the Colombian health sector. However, this solution is both biased and insufficient, as many of the most important biotech drugs have VMRs which are set well above the international price and because several other important products do not yet have a set VMR.

This information leads us to the conclusion that that the new National Drug Policy (Política Farmacéutica Nacional) and the new price regulation regime be set so that the current government can improve on them and implement other mechanisms allowing, at the least, the prices to be set to international standards and to possibly develop conditions where the cost of these drugs are favorable in Colombia.

On the use of parallel imports as a flexibility stipulated in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), it can be said that the mere threat of its application produced some initial results (Roche Agreement), but we were unable to know the true scope of its application in Colombia. This study could not measure its true effect, because it is based on reports from laboratories and parallel imports are not detectable in data provided. The use of other flexibilities provided in TRIPS, such as compulsory licensing, which has been successfully applied in some countries, to this date, have not been applied in Colombia<sup>18</sup>.

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<sup>18</sup> [Capítulo 4](#): The invisible threat: trade, intellectual property and pharmaceutical regulations in Colombia



Colombia's only experience with the alternative flexibilities was when, in 2008, the Bureau of organizations working on HIV / AIDS (Mesa de Organizaciones que trabajan en VIH/SIDA), The Colombian Network of People living with HIV (la Red Colombiana de Personas que viven con VIH), as well as the IFARMA foundation (las fundaciones IFARMA) and Mission Health (Misión Salud) filed a formal request to the President of Colombia, The Ministry of Social Protection and the Superintendent of Industry and Commerce to issue a compulsory license of the drug Lopinavir-Ritonavir (Kaletra) for reasons of public interest.<sup>19</sup> The petition was denied and these civil society organizations pushed forward a class action suit that was recently denied (02/29/2012) by the 37<sup>th</sup> Civil Court in the Bogotá circuit.<sup>20</sup> The sentence, which was partially favorable for the petition, was appealed by both parties and continues its legal course. We mention this case in this report because it is an unprecedented move in Colombia, where civil society organizations help steer the course of public health advocacy, which should be run by the government.

Other patient organizations have adopted, without reservations, different approaches to the government initiatives that seek to issue regulations for the registration of biopharmaceuticals in Colombia and did not hide their intentions to open up competition in the market. In other cases, some patient organizations have adopted a position coinciding with the AFIDRO<sup>21</sup> (the union of multinational owners of biotech monopolies in Colombia) whose spokesmen were quick to say that Colombia would become a "paradise for poor quality medicines."<sup>22</sup>

The possibilities for opening up the biotech market with the flexibility mechanisms of intellectual property protection are minimal, as the manufacturing process is also patented. However, test data protection is one possible mechanism where something can still be done in Colombia, as Act 2085 extended data protection for 5 years while the Obama administration has already accepted 12. Still, the use of the clause citing "considerable effort" in the Colombian standards, and intends to reward investment in the development of technology, has not been applied properly and, in 122 applications for the protection of data, it has been awarded 81% of the time<sup>23</sup>. This generosity in granting data exclusivity (which can be seen as equivalent to granting an express patent) is delaying the entry of biotech drugs into the market and substantially threatens the financing of the healthcare system.

In the same vein, the opening of the market to "bio-similar" drugs is a subject that has been hotly debated in Colombia, although the annual report from the United States Trade Representatives, in relation to special law 301 of the US trade act (Pharmaceutical Research and Manufacturers of America (PhRMA), 2012),<sup>24</sup> states that the regulation has been issued without further discussion.<sup>25</sup> A second draft has been circulated and a summary comparison with the previous one seems to show better reception so far.

Given the partial utility of the above measures, the FMC proposed studying two additional mechanisms in Colombia; negotiating the price of entry and centralized purchasing. Negotiating

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<sup>19</sup> [Nota de prensa](#) July 17th, 2008

<sup>20</sup> <http://www.citizen.org/documents/Colombian%20court%20decision%20summary.pdf>

<sup>21</sup> Campaign de AFIDRO en [Nota de prensa 1](#), [Nota de prensa 2](#), [Nota de prensa 3](#), [Presentación Foro](#).

<sup>22</sup> [Nota de Portafolio](#).

<sup>23</sup> [Impacto de 10 años de protección de datos en medicamentos en Colombia](#), IFARMA.

<sup>24</sup> [Biológicos y biotecnológicos: una oportunidad para Colombia](#), Dr. Luis Guillermo Restrepo V.

<sup>25</sup> [2° Proyecto](#) and the [Resumen comparativo](#).

the price of entry, for prices equal to or less than an international reference price, would allow companies access to the Colombian market in return for setting these prices and centralized purchasing would improve Colombia's hand in negotiations and allow for purchasing power because of the scale such purchases would have. According to the FMC, the experiment failed to pass CAPREMED, but the idea of central purchasing should not be abandoned, but the idea should be corrected for better implementation.

As for measures to regulate consumption, it should be noted that Rituximab and Trastuzumab were originally included in the Compulsory Health Plan (POS), through Accord 29 of the Regulatory Commission on Health (Comisión de Regulación en Salud, CRES) on December 30<sup>th</sup>, 2011. En cuanto a las medidas para regular el consumo, debe resaltarse la inclusión inicial de Rituximab y Trastuzumab en el Plan Obligatorio de Salud (POS), mediante el Acuerdo 29 de la Comisión de Regulación en Salud (CRES) de 30 de diciembre de 2011.

This measure has caused the role of the EPS to change, as the passing changed the EPS from "being part of the problem" to "being part of the solution," in relationship to these two important monoclonal antibodies. Previously the EPS could recover these biotech drugs "at any price" and they have to use UPC funds, which are much less elastic. If this experiment proves to be successful, it is expected that many more medications will be included in the POS

Finally, the issue of recoveries completely overshadows the funding landscape available for biotech drugs. As mentioned in the introduction, there is no information that allows us to know the actual amount paid during the term of the "2005 fidufosyga Consortium." The National Superintendent of Health, in response to a FMC request on the right to health, said that this amount exceed COP 5.8 trillion only in the years 2007 to 2010. The Consortium and the Ministry of Industry, also responding to the FMC petition, concluded by saying that the magnetic information of the recoveries does not match the physical documentation. The new finance administrator of the SAYP consortium said he would be reviewing the information, but so far has no delivered on this promise.

In this context, the magnitude of the problem can be seen by analyzing three infographics released by the FMC, which show the estimated overcharges (mentioned earlier in this report) and the information on recoveries for the three monoclonal antibodies developed by Roche. The first, Rituximab (Mabthera®) is emblematic because it is based on data that has been questioned by the FMC and shows per unit values of COP 130 billion (for each ampule). This was corrected, as it was in another sample of 170 recoveries with values over COP 100 billion

**Figures 3 - 5: Infographics of the overcharges and recoveries of the three most important Monoclonal Antibodies**



View the infographics for [Rituximab \(Mabthera®\)](#), [Trastuzumab \(Herceptin®\)](#), [Bevacizumab \(Avastin®\)](#).

According to these infographics, in the period 2008 to 2011, the spending on Rituximab totaled COP 472 billion, for Trastuzumab it totaled COP 304 billion and for Bevacizumab totaled COP 201 billion. This represents the true financial hemorrhaging of the system.

The specific case of the three biotech drugs mentioned above can be partially resolved by including the first two in the POS while the third can exit the market (based on the fact that the FDA has denied it utility for the approved clinical indications in Colombia). The other biotech drugs, however, remain in an apocalyptic state.

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