IMPACT OF DATA EXCLUSIVITY ON MEDICINES IN COLOMBIA

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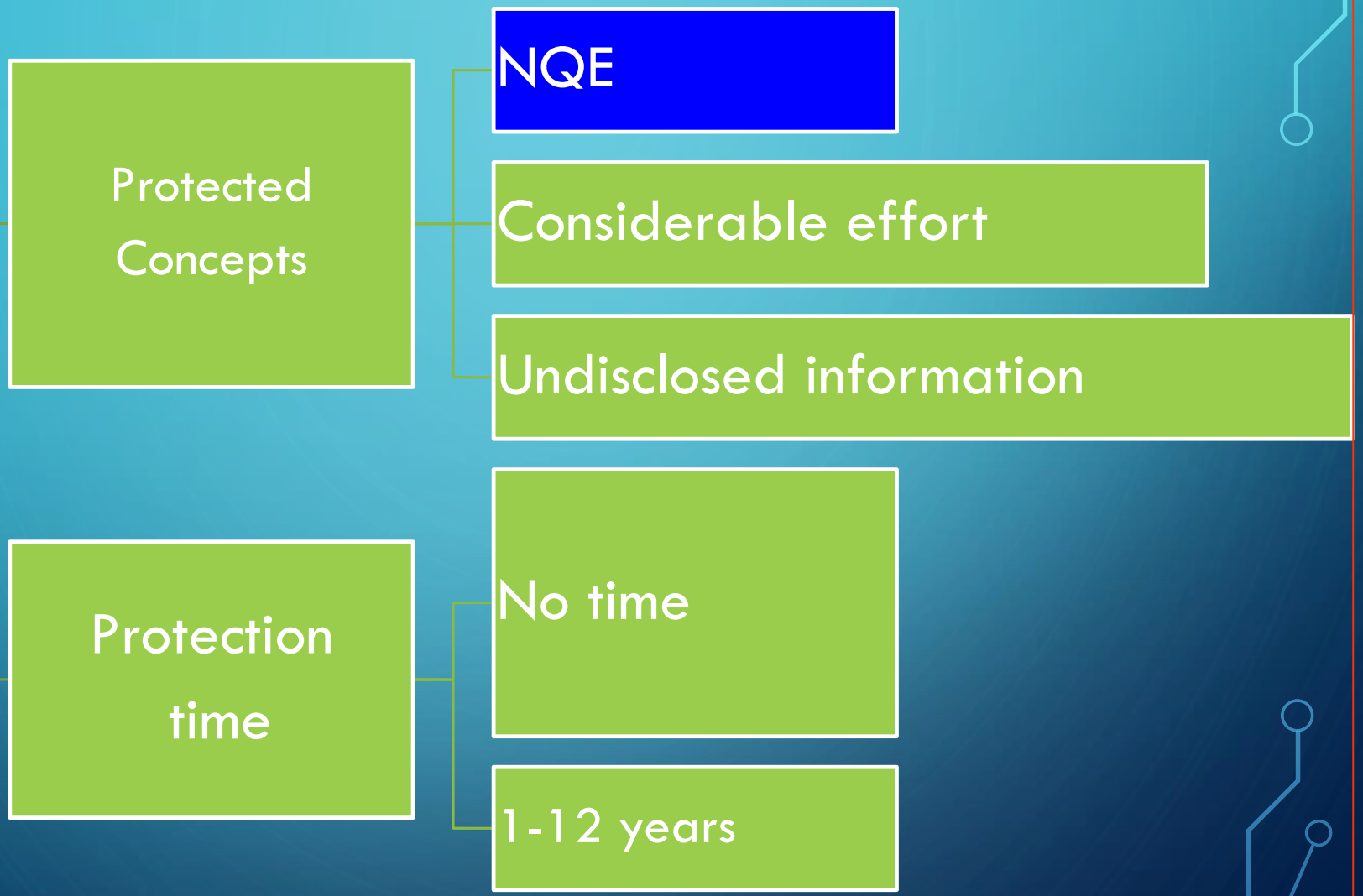
DATA EXCLUSIVITY IN COLOMBIA

- ✓ Decreto 2085/ 2002.
- ✓ FTA implementation plan with the United States as a condition of Plan Colombia (initiative against drugs and promotion of peace).
- ✓ ASINFAR (Association of national pharmaceutical industries) filed lawsuit with the Andean Court of Justice, for considering it contrary to TRIPS and Decision 486 (intellectual property in the countries of the Andean community)
- ✓ PhRMA (Pharmaceutical Research and Manufacturers of America, request that Colombia remain on the watch list for Special Report 301 of 2011.

IMPACT OF 10 YEARS OF DATA EXCLUSIVITY ON MEDICINES IN COLOMBIA

DATA EXCLUSIVITY

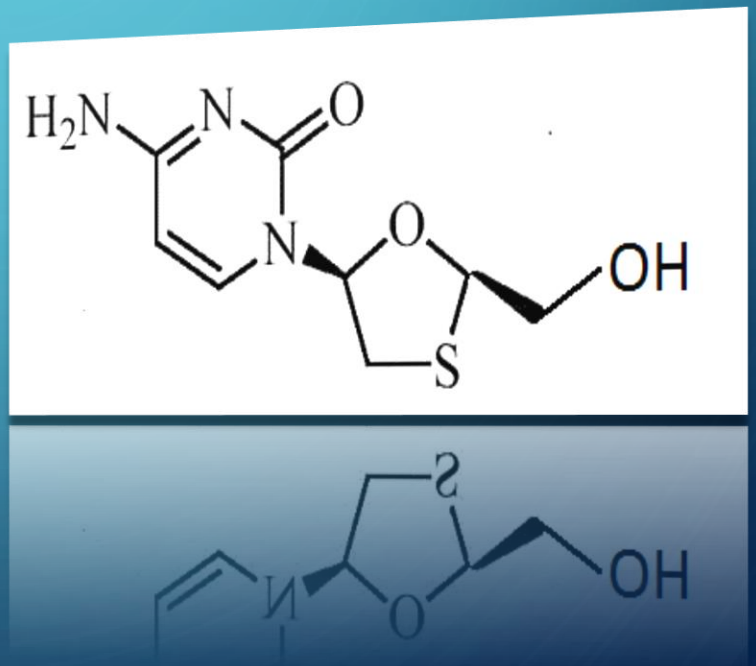


GENERAL INFORMATION ON MOLECULES WITH DATA PROTECTION IN COLOMBIA FOR THE PERIOD 2002 - 09/2011

Request	Number	Percentage
Granted	99	81,1%
Denied	5	4,1%
In study	18	14,8%
Data exclusivity	122	100%
NQE	114 (8 In pharmacological study)	
Medicines that included these NQE	180	
Defeated	43	
New medicines registered in Colombia	10.873	

Source: http://web.invima.gov.co/portal/faces/index.jsp?id=11488

NEW CHEMICAL ENTITY



Definition NQE	# of protected medicines in Colombia (May 2003 - June 2011)
A drug that does not contain the previously approved active chemical entity and that involves considerable effort	99
That has not been previously described in the literature.	22 (99 minus 77 who have reported literature before their data protection)
That provides significant clinical benefits over existing therapies.	52 (99 minus 47 that according to the FDA do not represent considerable therapeutic contribution or were not approved)
The two conditions: No previous report in the literature and contribution of significant clinical benefits on existing therapies.	11 (99 minus 77 medications described in the literature, minus 11 that do not represent an important therapeutic contribution)

DATA EXCLUSIVITY IN COLOMBIA 2003 - 2011

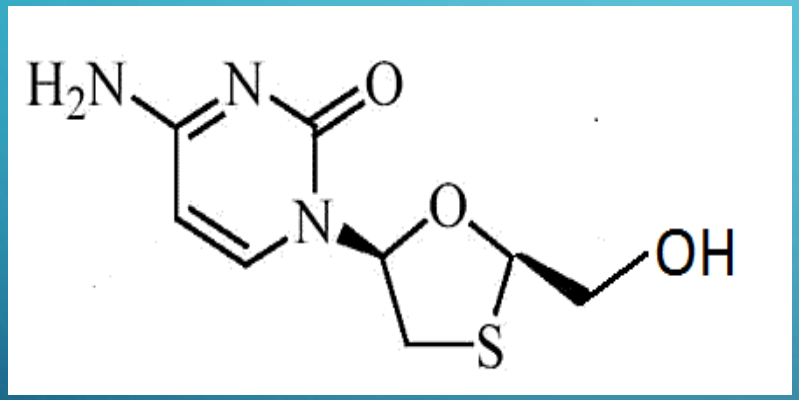
Year	NQE Approved	Protected	Requested	Denied	In study	In force	Defeated
2003	7	7	7	0	0	7	0
2004	13	13	15	1	0	20	0
2005	19	15	15	0	0	35	0
2006	10	9	9	0	0	39	5
2007	20	10	12	2	0	47	2
2008	12	19	19	0	0	53	13
2009	13	9	11	2	0	62	0
2010	15	11	15	0	4	58	15
2011	5	6	11	0	6	56	8
In pharmacological study		-	8	0	8	0	0
TOTAL	**114**	**99**	122	5	18	56	43

ORIGIN OF DATA EXCLUSIVITY HOLDERS IN COLOMBIA

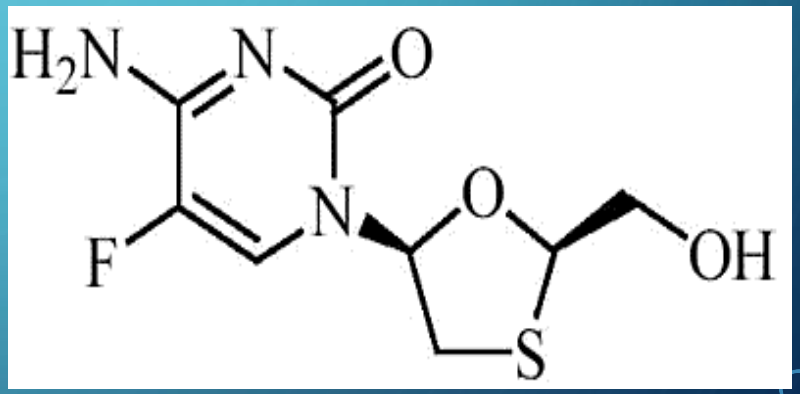
Country of origin of the holder	Number of protections granted	%
United States	41	41,41
Switzerland	16	16,16
Germany	13	13,13
Belgium – Switzerland	10	10,10
United Kingdom	9	9,09
Colombia	3	3,03
Argentina	3	3,03
France	2	2,02
Belgium	1	1,01
Sweden	1	1,01

CONSIDERABLE EFFORT

LAMIVUDINE



EMTRICITABINE

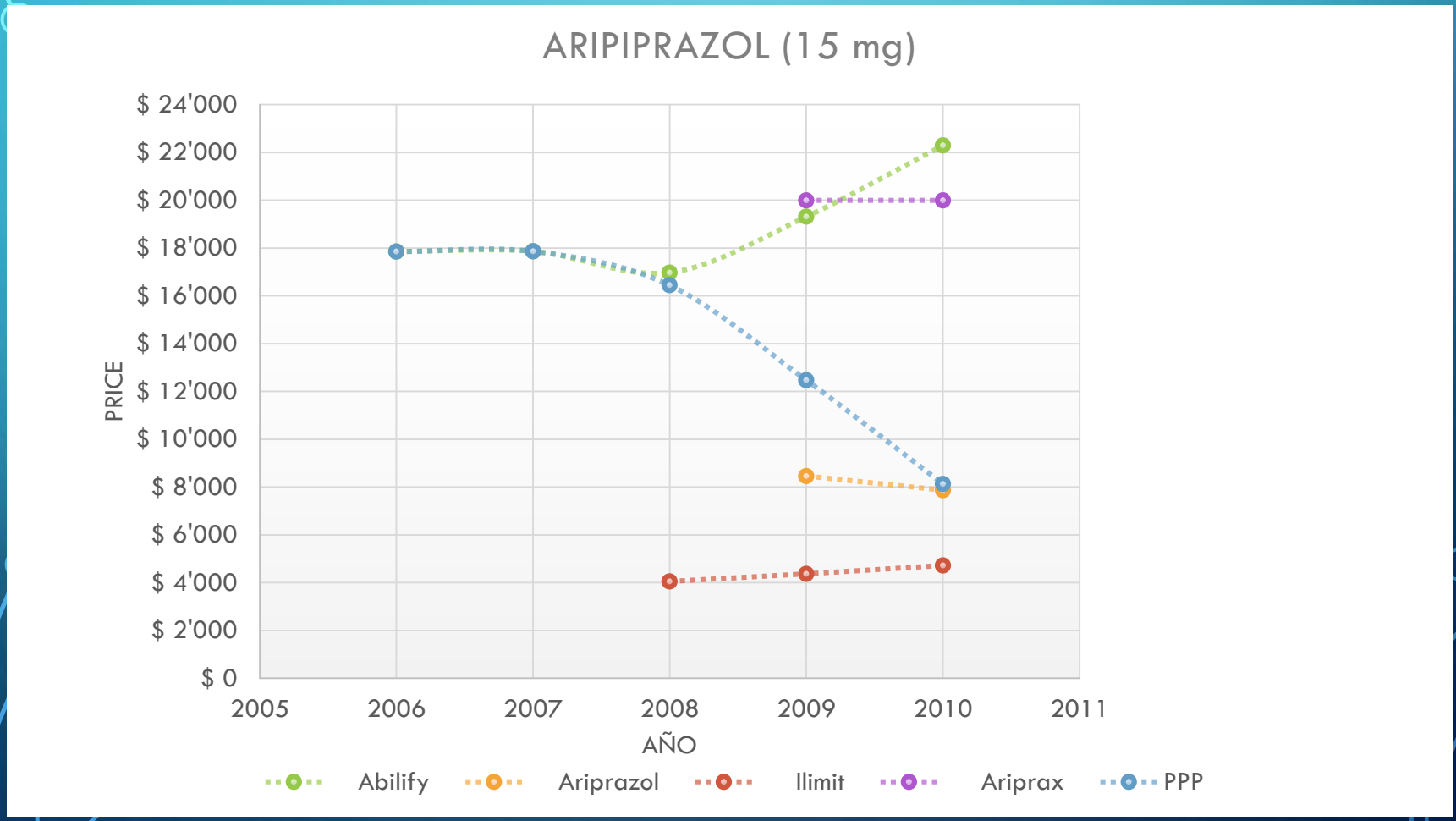


CONSIDERABLE EFFORT

In Colombia:

- *The time invested in R&D.*
- *The money invested in research.*
- *The technology used in research.*
- *Information on human resources.*

EFFECT OF COMPETITORS ON THE PRICE



COMPARISON WITH REGISTRATION DATES IN VENEZUELA FOR CHEMICAL ENTITIES WITH DATA PROTECTION IN COLOMBIA

	Registered first in Venezuela					
	Between 0-1 years	Between 1-2 years	Between 2-3 years	Between 3-5 years	More than 5 years	Registered first in Colombia
Number of medications	29	0	0	0	0	22
Percentage	57%	0%	0%	0%	0%	43%

	Registered first in Colombia		
	Between 0-1 años	Between 1 y 5 años	More than 5 years
Number of medications	9	12	1
Percentage	18%	24%	2%

EXHAUSTION OF THE RIGHT

Possibility of requiring that the registration of a new product with exclusive PD, has a time limit to be registered in the country, after being registered in any other country in the world. (FTA United States: 5 years)

EXCEPTIONS

- ✓ *New uses and second uses.*
- ✓ *Novelties or changes on pharmaceutical forms, indications or second indications, new combinations of known chemical entities, formulations, dosage forms, routes of administration.*
- ✓ *Modifications that imply changes in pharmacokinetics, marketing and packaging conditions and new presentations.*

DATA EXCLUSIVITY– RESULTS IN COLOMBIA

- Only 13 of the 43 protections expired had, at the date of consultation (September 1, 2011), competing products registered in the INIVIMA, or 30%. This evidences a lack of response of the manufacturers of competing medicines before the expiration of the protections.
- The first competitor to register once the protection expires takes an average of 11.5 months, which can be considered as a good indication of the competitors' response when they are interested in the market that represents a specific active principle.

DATA EXCLUSIVITY– RESULTS IN COLOMBIA

- Impact on the health system for the period 2003-2011, was $ 396 million USD, annual value of health insurance of 146,000 Colombians.
- Only 3% were industries with national capital.

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