REDEL STUDY: DIFFERENCES IN REIMBURSEMENT DELAYS IN CEE COUNTRIES

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Background

Access to original medicines is crucial to patients and supports the business goals of the pharmaceutical companies. Delay in the reimbursement process limits both of them, time to reimbursement of innovative medicines is significantly longer than recommended by the Transparency Directive. This study reviews the differences of reimbursement delays of the original outpatient care products in CEE countries (Austria, Bulgaria, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia and Slovenia). The subjects of the study are the original drugs authorized by the European Medicines Agency (EMA) or any national authorities of the above mentioned countries between 1st January 2007 and 1st July 2013. These originals were checked if they are part of the reimbursement system in the researched countries and the start of reimbursement is between 1st January 2010 and 1st July 2013. The reimbursement delays are counted from the time difference of the marketing authorization date and the beginning date of the reimbursement in each country.

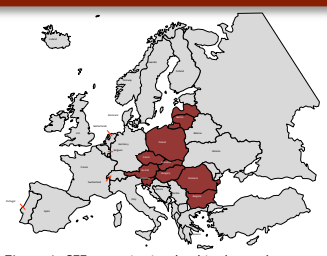

Figure 1. CEE countries involved in the study

Methods

The bases of comparison were 216 products and their ATC codes selected from the database of the EMA which were granted a marketing authorization between 1st January 2007 and 1st July 2013. After a four-level cleaning process of the database the EMA list contained 149 original ATCs. Additionally, 44 other INNs were found at least in one national list of the studied countries while comparing the EMA list with the national lists. In the case of these products the research studied the dates, when countries adopted them into their reimbursement system. The adoption was the subject of the study between 1st January 2010 and 1st July 2013. The level of accuracy varies between 30 and 90 days in the case of the national reimbursement data sources, depending on publication frequency. The analysis was conducted by different aspects like country, active substance and marketing authorization holder (MAH). The following indicators were calculated in the study: REDEL - the delay between marketing authorization date and reimbursement date; INNREIMB - the number of reimbursed INNs according to a specific country or MAH; SR - Success Rate as the ratio of reimbursed INNs to examined INNs.

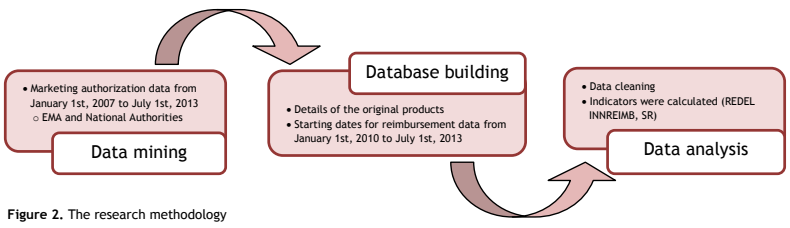

Figure 2. The research methodology

Results

The overall SR results vary from 6.7% to 72.6%. Slovenia, Slovakia, Czech Republic and Austria are on the top while Lithuania, Poland and Romania stand the end of the line based on SR. The results show, that even threefold differences between the studied countries can be present regarding the reimbursement delay. While an average of 403 days elapses between the marketing authorization and the starting date of reimbursement (mean of 76 products) in Slovenia, the same time is 1295 days (mean of 21 adoptions) in Poland. In addition to Slovenia, Austria (443 days), Slovakia (469 days) and Bulgaria (570 days) are in forefront according to REDEL. The middle range of the studied countries are formulated by Hungary (667 days), the Czech Republic (699 days) and Estonia (821 days), while Latvia (821 days), Lithuania (1007 days) and Romania (1052 days) are in the last third ahead of Poland. The average value is 632 days. In the ranking made by therapeutic subgroups, the group named antibiotics and chemotherapeutics for dermatological use (ATC 2nd level - D06) reached the first place, while antiinflammatory and antirheumatic products (ATC 2nd level - M01) finished in the second place based on 4 adoptions with an average of 298 days. The REDEL values are also ranked by MAHs, where the grand average is 635 days. The average REDEL values vary from 227 to 2370 days. In average days of REDEL, top performers have only one new ATC.

REDEL

Country

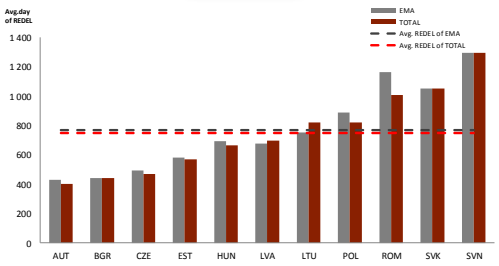

Figure 3. REDEL results by countries

SR

Count of INN appears in reimbursement system					
Country	01.01.2007 - 07.01.2013				
	EMA	SR	TOTAL	SR	TOP*
Austria (AUT)	59 (149)	39,6%	66 (172)	38,4%	5.
Bulgaria (BGR)	57 (149)	38,3%	59 (151)	39,1%	4.
Czech (CZE)	81 (149)	54,4%	99 (167)	59,3%	2.
Estonia (EST)	23 (149)	15,4%	26 (165)	15,8%	8.
Hungary (HUN)	52 (149)	34,9%	59 (182)	32,4%	6.
Latvia (LVA)	25 (149)	16,8%	33 (178)	18,5%	7.
Lithuania (LTU)	12 (149)	8,1%	19 (178)	10,7%	10.
Poland (POL)	23 (149)	15,4%	23 (149)	15,4%	9.
Romania (ROM)	10 (149)	6,7%	10 (149)	6,7%	11.
Slovakia (SVK)	86 (149)	57,7%	108 (183)	59,0%	3.
Slovenia (SVN)	111 (149)	74,5%	130 (179)	72,6%	1.

*Toplist are based on SR of TOTAL

Table 3. SR results by countries

MAH

TOP	MAH	Country											MAH average
		AUT	BGR	CZE	EST	HUN	LVA	LTU	POL	ROM	SVK	SVN	
1.	DAIICHI	227											227
2.	LEO											231	231
3.	BOEHRINGER	248	171	319	349	334	262	950		248	125		294
4.	BIOGEN									439	165		302
5.	GILEAD	308									304		306
6.	CARDIOME		428							212	302		314
7.	BMS/PFIZER	228		259							498		328
8.	THERAMEX										338		338
9.	GRÜNENTHAL			567						537	-43		354
10.	THEA			499						417	155		357
...	...	...	...	...	...	...	...	...	...	...	...	...	...
	Country average	443	570	699	821	667	821	1007	1295	1052	469	403	635

Table 1. REDEL results by MAH

TOP	MAH	Overview (01.01.2010 - 07.01.2013)				SR
		INNREIMB		EXAMINED INNs		
		DIST.COUNT	ALL CASES	DIST.COUNT	ALL CASES	
1.	ORION	1	7	1	11	64%
2.	BOEHRINGER	4	27	4	44	61%
3.	SANTEN	1	6	1	11	55%
4.	UCB	2	10	2	22	45%
5.	BMS/ASTRA	2	14	3	33	42%
6.	AMGEN	3	13	3	33	39%
7.	GENZYME	1	4	1	11	36%
8.	HRA	1	4	1	11	36%
9.	VIIV	1	4	1	11	36%
10.	GSK	10	49	13	143	34%
...	...	...	...	...	...	...
	SUM	142	421	175	1925	22%

Table 4. SR results by MAH

ATC

TOP	INN - International Nonproprietary Name	INNs average REDEL
1.	D06 - ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE	231 (1)
2.	M01 - ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	298 (4)
3.	G04 - UROLOGICALS	353 (12)
4.	R03 - ANTI-ASTHMATICS	356 (14)
5.	M05 - DRUGS FOR TREATMENT OF BONE DISEASES	360 (9)
6.	B02 - ANTIHEMORRHAGICS	388 (10)
7.	J01 - ANTIBACTERIALS FOR SYSTEMIC USE	402 (2)
8.	N07 - OTHER NERVOUS SYSTEM DRUGS	419 (5)
9.	N02 - ANALGESICS	432 (6)
10.	M09 - OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM	487 (1)
...	...	...
34.	N05 - PSYCHOLEPTICS	1125 (4)
35.	H01 - PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES	1143 (3)
36.	A16 - OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	1168 (11)
37.	C02 - ANTIHYPERTENSIVES	1256 (5)
38.	M04 - ANTIGOUT PREPARATIONS	1359 (3)

Table 2. REDEL results by ATC 2nd level

Macroeconomic indicators

The last phase of the research observed connections between the reimbursement delay and various macroeconomic indicators of the countries. There is a determining correlation between the reimbursement delay and the public expenditures on pharmaceuticals, as generally with indicators relating the financing of healthcare, while the correlation between other indicators of countries (e.g. Global Competitiveness Index) are considered to be statistically non-significant.

Conslusions

The results show that even threefold difference exists among the studied countries with regards to the reimbursement delay. An average of almost two years elapse until a producer can have the given product adopted into the reimbursement system in a country (the REDEL steadily increasing in the studied period, while the number of reimbursed products is decreasing). Total REDEL ranging between 403 (SLO) to 1295 (POL) days, while the overall SR varies from 7% (Romania) to 73% (Slovenia). Correlation between REDEL and public expenditure on pharmaceuticals is found, unlike other macroeconomic indicators. According to the results company efficiency very much depends on product portfolio. Further extensions in the scope of the study are possible, like study period or geographic extension, broadening the study with application delay analysis or to analyze different subsets of products (real innovation, incremental innovation, me-too).

References

1. EMA's Marketing Authorization database: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/epar_search.jsp&mid=WC0b01ac058001d124 Last visit: 2013.10.28.
2. Marketing authorization and reimbursement national lists of the studied countries
3. Public expenditure on pharmaceuticals: http://www.oecd-ilibrary.org/
4. The Global Competitiveness Index: http://www.weforum.org/

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