

Censorship masquerading as “transparency”: the EMEA assessment report on rimonabant

We often ask the European Medicines Agency (EMA) for information that is not available on the agency’s website. Their response in the case of rimonabant, a drug that has now been withdrawn from the market, is an example of how drug regulatory agencies practice censorship.

The EMA provided us with several documents, including a report from the Swedish agency (Läkemedelsverket “Acomplia Final Assessment Report”). Yet, only 3 of the 68 pages in this report were legible: the rest of the text has been systematically blacked out, line by line, even including the date of the report.

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Prescr Int 2009 ; 18 (103) : 231.

Date: [REDACTED]

Acomplia/Zimulti

EU/1/06/344/001-009

Final Assessment Report [REDACTED]

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1/25/20	Deposited			75.00	75.00	125.00
2/1/20	Withdrawal	25.00	25.00			100.00
2/10/20	Deposited			150.00	150.00	250.00
2/15/20	Withdrawal	100.00	100.00			150.00
2/20/20	Deposited			200.00	200.00	350.00
2/25/20	Withdrawal	75.00	75.00			275.00
3/1/20	Deposited			125.00	125.00	400.00
3/10/20	Withdrawal	150.00	150.00			250.00
3/15/20	Deposited			100.00	100.00	350.00
3/20/20	Withdrawal	80.00	80.00			270.00
3/25/20	Deposited			180.00	180.00	450.00
4/1/20	Withdrawal	120.00	120.00			330.00
4/10/20	Deposited			90.00	90.00	420.00
4/15/20	Withdrawal	60.00	60.00			360.00
4/20/20	Deposited			110.00	110.00	470.00
4/25/20	Withdrawal	90.00	90.00			380.00
5/1/20	Deposited			130.00	130.00	510.00
5/10/20	Withdrawal	110.00	110.00			400.00
5/15/20	Deposited			160.00	160.00	560.00
5/20/20	Withdrawal	140.00	140.00			420.00
5/25/20	Deposited			190.00	190.00	610.00
6/1/20	Withdrawal	170.00	170.00			440.00
6/10/20	Deposited			210.00	210.00	650.00
6/15/20	Withdrawal	190.00	190.00			460.00
6/20/20	Deposited			240.00	240.00	700.00
6/25/20	Withdrawal	220.00	220.00			480.00
7/1/20	Deposited			270.00	270.00	750.00
7/10/20	Withdrawal	250.00	250.00			500.00
7/15/20	Deposited			300.00	300.00	800.00
7/20/20	Withdrawal	280.00	280.00			520.00
7/25/20	Deposited			330.00	330.00	850.00
8/1/20	Withdrawal	310.00	310.00			540.00
8/10/20	Deposited			360.00	360.00	900.00
8/15/20	Withdrawal	340.00	340.00			560.00
8/20/20	Deposited			400.00	400.00	960.00
8/25/20	Withdrawal	380.00	380.00			580.00
9/1/20	Deposited			450.00	450.00	1030.00
9/10/20	Withdrawal	430.00	430.00			600.00
9/15/20	Deposited			500.00	500.00	1100.00
9/20/20	Withdrawal	480.00	480.00			620.00
9/25/20	Deposited			550.00	550.00	1170.00
10/1/20	Withdrawal	530.00	530.00			640.00
10/10/20	Deposited			600.00	600.00	1240.00
10/15/20	Withdrawal	580.00	580.00			660.00
10/20/20	Deposited			650.00	650.00	1310.00
10/25/20	Withdrawal	630.00	630.00			680.00
11/1/20	Deposited			700.00	700.00	1380.00
11/10/20	Withdrawal	680.00	680.00			700.00
11/15/20	Deposited			750.00	750.00	1450.00
11/20/20	Withdrawal	730.00	730.00			720.00
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1. The first step in the process is to identify the problem or issue that needs to be addressed. This involves gathering information and understanding the context of the problem.

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Date: [REDACTED]

10 Risk Management Plan

The fourth version of the European RMP of rimonabant, is submitted as initially planned [REDACTED]

Compared to the previous European RMP (third version), dated 18-Aug-2007, the major changes regarding the content are as follows:

- The list of identified and potential risks has been updated with the addition of the identified risk of psychotic disorders. Otherwise, data about the already listed risks in the safety specifications have been updated with:

- integration of a newly completed study ([REDACTED]) in the pool of completed phase III clinical studies in the obesity / type 2 diabetes program.
- review of serious adverse events from 4 phase I and 16 phase III and IV studies that are ongoing during the period covered by PSUR 3.
- epidemiology results [REDACTED] presenting background incidence rates of depression, suicide death and suicide attempts, anxiety, seizures and cardiovascular events in an obese American population. Results from depression among smokers in the [REDACTED] cohort are also provided, as planned in the initial European RMP, although smoking cessation is not an indication for rimonabant.
- results from new waves of prescription surveys done in 3 European countries ([REDACTED]) after the changes in the SPC in July 2007 reinforcing the contraindication and cautions in depressed patients, as well as results describing the use of rimonabant in longitudinal medical record databases: [REDACTED]

- The Pharmacovigilance Plan has been updated as follows:

- update in the program of life cycle management studies,
- submission of the protocol of the study assessing the background rates of suicidal events in the [REDACTED] database,
- submission of the protocol for [REDACTED] assessing the association between nonrecurrent suicide attempts and the use of rimonabant [REDACTED] and [REDACTED]
- A new pharmacoepidemiological study [REDACTED]

- The risk minimization plan has been updated regarding both the description of the educational program and the tools to measure the effectiveness of minimization, as follows:

- the description of the communication process through which the MAH conveys the appropriate labeling information to the prescribers has been specified, focusing on actions that are different from promotional activities.
- re-submission of the prescription survey protocol as originally provided in the first European RMP, updated with a new questionnaire for prescription surveys taking into account the changes in labeling of July 2007.
- submission of an outline for a prescription study [REDACTED], and a protocol for “rimonabant in Clinical Practice”, a drug utilization survey in primary care [REDACTED]

Date: [REDACTED]

[REDACTED]
Assessor's comment: [REDACTED]

Regarding the synopsis [REDACTED]. The synopsis describes the various approaches for a case-control study to assess the risk of suicide attempts (SA) in association with the use of rimonabant by using the [REDACTED] information system, i.e. definition and enrollment of cases and controls, exposure and risk factor ascertainment, data validation and power estimation. Overall, the [REDACTED] system seems to provide valuable resources to perform the study and to generate meaningful results. Also, the case-control methodology, in the briefly described aspects, appears adequate for the purpose of the study, yielding an 80 % power to detect a 2- to 3-fold increase of the risk for SA in users of rimonabant, given two different assumptions on the prevalence of rimonabant use in referents. There are many challenges foreseen in the conduct of the study, important ones being characterization of the psychiatric disorder in SA patients taking rimonabant and possible risk factors that could predispose exposed obese patients for SA. One crucial issue will be to address whether there is an independent effect of rimonabant from the effect of weight reduction per se in these obese patients. Therefore, detailed information on the the index psychiatric events and on relevant comorbidity will be important.

In summary, the study as described in the synopsis is broadly endorsed. However, a full and detailed protocol for the study is awaited. [REDACTED]

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Regarding the RMP

[REDACTED]

The results from the Drug Utilization Study [REDACTED] should be provided as soon as possible.

Timelines for the study Rimonabant In Clinical Practice should be provided by the company. This study could provide valuable data, provided there will be a sufficient size of study population.

The [REDACTED] Information System study as described in the synopsis is broadly endorsed. However, a full and detailed protocol for the study is awaited. [REDACTED]

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The protocol-or synopsis for the new pharmacoepidemiology study [REDACTED] should be provided by the company.

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TABLE 1
STANDARDIZATION OF THE DATA

Figure 1. The effect of the concentration of the polymer solution on the apparent viscosity of the polymer solution. The apparent viscosity of the polymer solution increases with increasing the concentration of the polymer solution.

the 1990s, the number of people in the United States who are 65 years of age or older has increased by 50 percent, and the number of people 75 years of age or older has increased by 100 percent. The number of people 85 years of age or older has increased by 200 percent. The number of people 95 years of age or older has increased by 400 percent. The number of people 100 years of age or older has increased by 1,000 percent. The number of people 105 years of age or older has increased by 2,000 percent. The number of people 110 years of age or older has increased by 4,000 percent. The number of people 115 years of age or older has increased by 8,000 percent. The number of people 120 years of age or older has increased by 16,000 percent. The number of people 125 years of age or older has increased by 32,000 percent. The number of people 130 years of age or older has increased by 64,000 percent. The number of people 135 years of age or older has increased by 128,000 percent. The number of people 140 years of age or older has increased by 256,000 percent. The number of people 145 years of age or older has increased by 512,000 percent. The number of people 150 years of age or older has increased by 1,024,000 percent. The number of people 155 years of age or older has increased by 2,048,000 percent. The number of people 160 years of age or older has increased by 4,096,000 percent. The number of people 165 years of age or older has increased by 8,192,000 percent. The number of people 170 years of age or older has increased by 16,384,000 percent. The number of people 175 years of age or older has increased by 32,768,000 percent. The number of people 180 years of age or older has increased by 65,536,000 percent. The number of people 185 years of age or older has increased by 131,072,000 percent. The number of people 190 years of age or older has increased by 262,144,000 percent. The number of people 195 years of age or older has increased by 524,288,000 percent. The number of people 200 years of age or older has increased by 1,048,576,000 percent. The number of people 205 years of age or older has increased by 2,097,152,000 percent. The number of people 210 years of age or older has increased by 4,194,304,000 percent. The number of people 215 years of age or older has increased by 8,388,608,000 percent. The number of people 220 years of age or older has increased by 16,777,216,000 percent. The number of people 225 years of age or older has increased by 33,554,432,000 percent. The number of people 230 years of age or older has increased by 67,108,864,000 percent. The number of people 235 years of age or older has increased by 134,217,728,000 percent. The number of people 240 years of age or older has increased by 268,435,456,000 percent. The number of people 245 years of age or older has increased by 536,870,912,000 percent. The number of people 250 years of age or older has increased by 1,073,741,824,000 percent. The number of people 255 years of age or older has increased by 2,147,483,648,000 percent. The number of people 260 years of age or older has increased by 4,294,967,296,000 percent. The number of people 265 years of age or older has increased by 8,589,934,592,000 percent. The number of people 270 years of age or older has increased by 17,179,869,184,000 percent. The number of people 275 years of age or older has increased by 34,359,738,368,000 percent. The number of people 280 years of age or older has increased by 68,719,476,736,000 percent. The number of people 285 years of age or older has increased by 137,438,953,472,000 percent. The number of people 290 years of age or older has increased by 274,877,906,944,000 percent. The number of people 295 years of age or older has increased by 549,755,813,888,000 percent. The number of people 300 years of age or older has increased by 1,099,511,627,776,000 percent. The number of people 305 years of age or older has increased by 2,199,023,255,552,000 percent. The number of people 310 years of age or older has increased by 4,398,046,511,104,000 percent. The number of people 315 years of age or older has increased by 8,796,093,022,208,000 percent. The number of people 320 years of age or older has increased by 17,592,186,044,416,000 percent. The number of people 325 years of age or older has increased by 35,184,372,088,832,000 percent. The number of people 330 years of age or older has increased by 70,368,744,177,664,000 percent. The number of people 335 years of age or older has increased by 140,737,488,355,328,000 percent. The number of people 340 years of age or older has increased by 281,474,976,710,656,000 percent. The number of people 345 years of age or older has increased by 562,949,953,421,312,000 percent. The number of people 350 years of age or older has increased by 1,125,899,906,842,624,000 percent. The number of people 355 years of age or older has increased by 2,251,799,813,685,248,000 percent. The number of people 360 years of age or older has increased by 4,503,599,627,370,496,000 percent. The number of people 365 years of age or older has increased by 9,007,199,254,740,992,000 percent. The number of people 370 years of age or older has increased by 18,014,398,509,481,984,000 percent. The number of people 375 years of age or older has increased by 36,028,797,018,963,968,000 percent. The number of people 380 years of age or older has increased by 72,057,594,037,927,936,000 percent. The number of people 385 years of age or older has increased by 144,115,188,075,855,872,000 percent. The number of people 390 years of age or older has increased by 288,230,376,151,711,744,000 percent. The number of people 395 years of age or older has increased by 576,460,752,303,423,488,000 percent. The number of people 400 years of age or older has increased by 1,152,921,504,606,846,976,000 percent. The number of people 405 years of age or older has increased by 2,305,843,009,213,693,952,000 percent. The number of people 410 years of age or older has increased by 4,611,686,018,427,387,904,000 percent. The number of people 415 years of age or older has increased by 9,223,372,036,854,775,808,000 percent. The number of people 420 years of age or older has increased by 18,446,744,073,709,551,616,000 percent. The number of people 425 years of age or older has increased by 36,893,488,147,419,103,232,000 percent. The number of people 430 years of age or older has increased by 73,786,976,294,838,206,464,000 percent. The number of people 435 years of age or older has increased by 147,573,952,589,676,412,928,000 percent. The number of people 440 years of age or older has increased by 295,147,905,179,352,825,856,000 percent. The number of people 445 years of age or older has increased by 590,295,810,358,705,651,712,000 percent. The number of people 450 years of age or older has increased by 1,180,591,620,717,411,303,424,000 percent. The number of people 455 years of age or older has increased by 2,361,183,241,434,822,606,848,000 percent. The number of people 460 years of age or older has increased by 4,722,366,482,869,645,213,696,000 percent. The number of people 465 years of age or older has increased by 9,444,732,965,739,290,427,392,000 percent. The number of people 470 years of age or older has increased by 18,889,465,931,478,580,854,784,000 percent. The number of people 475 years of age or older has increased by 37,778,931,862,957,161,709,568,000 percent. The number of people 480 years of age or older has increased by 75,557,863,725,914,323,419,136,000 percent. The number of people 485 years of age or older has increased by 151,115,727,451,828,646,838,272,000 percent. The number of people 490 years of age or older has increased by 302,231,454,903,657,293,676,544,000 percent. The number of people 495 years of age or older has increased by 604,462,909,807,314,587,353,088,000 percent. The number of people 500 years of age or older has increased by 1,208,925,819,614,629,174,706,176,000 percent. The number of people 505 years of age or older has increased by 2,417,851,639,229,258,349,412,352,000 percent. The number of people 510 years of age or older has increased by 4,835,703,278,458,516,698,824,704,000 percent. The number of people 515 years of age or older has increased by 9,671,406,556,917,033,397,649,408,000 percent. The number of people 520 years of age or older has increased by 19,342,813,113,834,066,795,298,816,000 percent. The number of people 525 years of age or older has increased by 38,685,626,227,668,133,590,597,632,000 percent. The number of people 530 years of age or older has increased by 77,371,252,455,336,267,181,195,264,000 percent. The number of people 535 years of age or older has increased by 154,742,504,910,672,534,362,390,528,000 percent. The number of people 540 years of age or older has increased by 309,485,009,821,345,068,724,781,056,000 percent. The number of people 545 years of age or older has increased by 618,970,019,642,690,137,449,562,112,000 percent. The number of people 550 years of age or older has increased by 1,237,940,039,285,380,274,899,124,224,000 percent. The number of people 555 years of age or older has increased by 2,475,880,078,570,760,549,798,248,448,000 percent. The number of people 560 years of age or older has increased by 4,951,760,157,141,521,099,596,496,896,000 percent. The number of people 565 years of age or older has increased by 9,903,520,314,283,042,199,193,993,792,000 percent. The number of people 570 years of age or older has increased by 19,807,040,628,566,084,398,387,

[illegible]

[illegible]

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TABLE 1. *Continued*

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Date: [REDACTED]

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Date: [REDACTED]

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