

Censorship masquerading as "transparency": the EMEA assessment report on rimonabant

We often ask the European Medicines Agency (EMEA) 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 Their response in the case of rimonabant, a drug that has now been withdrawn from the market, is an example of how drug regulatory agencies practice censorship.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 EMEA 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.

©Prescrire

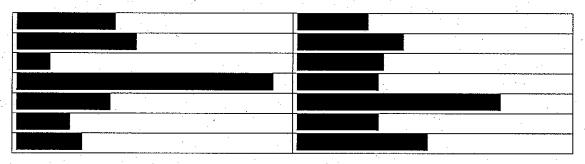
Prescr Int 2009; 18 (103): 231.



Acomplia/Zimulti

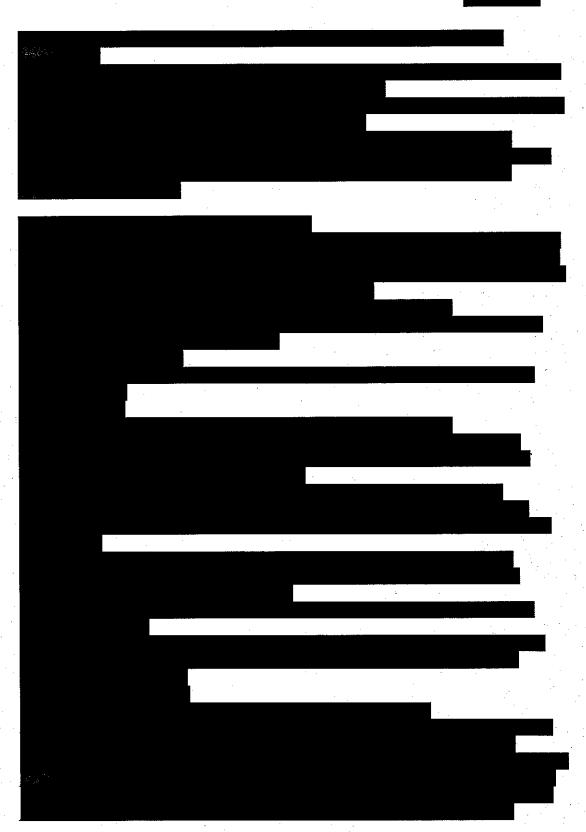
EU/1/06/344/001-009

Final Assessment Report

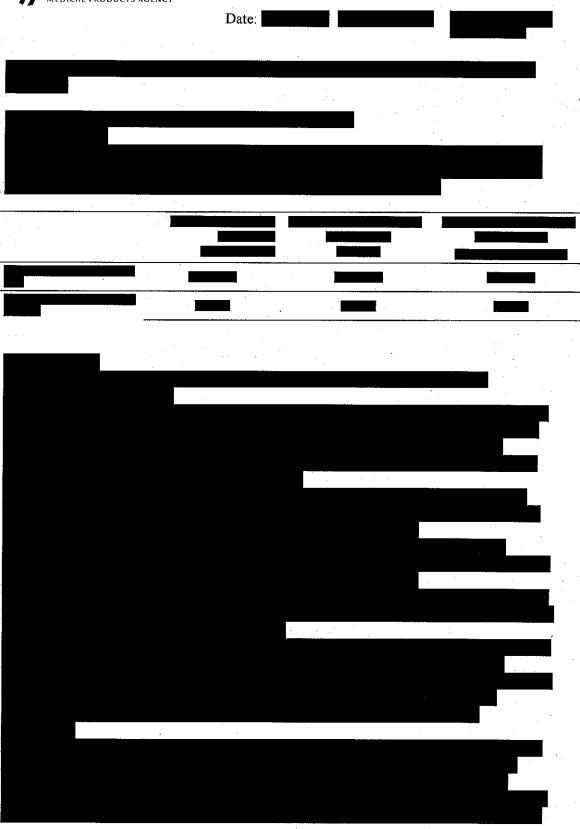












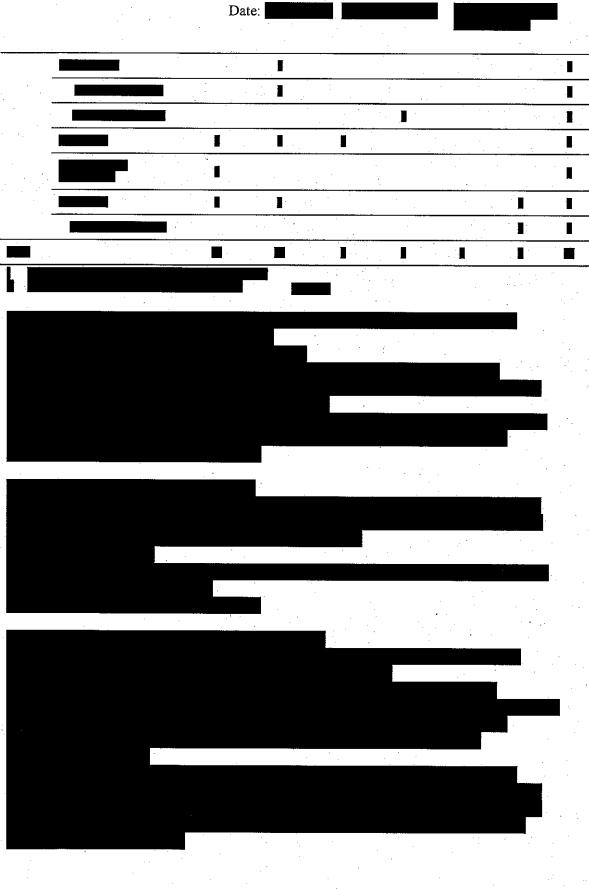




ı ı I

Date:







. . 7 (68)











	. * 			*	
				<u></u>	
				,	
		· ·		<u> </u>	
	· I			· I	
	<u> </u>		1		
	<u> </u>		·	·	<u> </u>
	<u>_</u>	· · · · · · · · · · · · · · · · · · ·			
	—	<u> </u>		<u> </u>	
			×		<u> </u>
	1		· · ·		-
	I				-
				- -	<u> </u>
				<u>-</u>	<u> </u>
			. 1		
·		I	3		
]				
	1				■
	-				
	i i			*	
				-	[
	I			· . I	
				. 1	
		· ···		I	
		<u> </u>			
		<u> </u>			
		<u> </u>			
	1				<u>.</u>
	: <u> </u>				<u> </u>
	. J		· · · · · · · · · · · · · · · · · · ·	• .	
	<u> </u>		· · · · ·		I



Date: I 1 F Ï ı











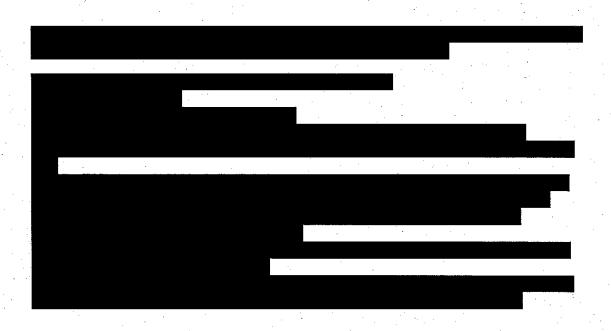
			-
I I	I		
			1
			1
	1		<u> </u>
· I	:		
· : I			
		1	
	1 1	-	1
<u>I</u>	· ·		I
			I
	•		
-			<u> </u>



·				
			I	
			I	1
	I I			
				<u> </u>
		I .	■ ·	
				1
		1	· · ·	<u>II</u>
			. ■	•
				ı
				-
	1			
				· I
				1
			 ı	
			* .	
	I		ı	1
				1
			ı	. J



 	<u> </u>
	I
- :	1
	1
•	
-	
	1
<u> </u>	









	•		Date.					
	2					e .		
					,		•	
	-							•
		٠.	•					
				•				,
								• •
•	•			÷		•		
			1					
			-					
	-							
			٠, .					
				`				•
		·		·		· ·		
			e se j					





Date: I I 23 (68)















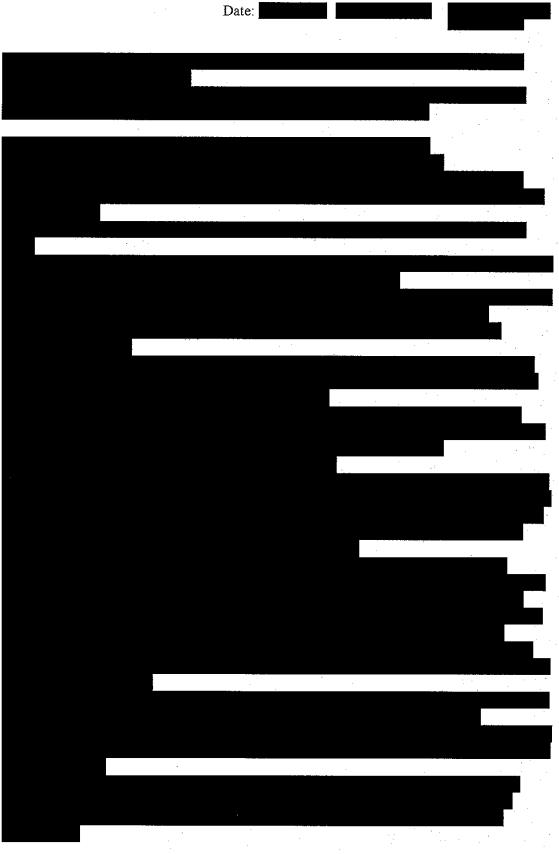




	Da	ite:			
		•	•		
				· · · · ·	
				·	
					 .
					
:					
			·	I	
					· · · · · ·
L Branch					
-					
		•			
<u> </u>					
		• 			
				=	
				. <u> </u>	
				_	
	·			<u> </u>	
		* 1.	·		
	· · · · · · · · · · · · · · · · · · ·				
	· · · · · · · · · · · · · · · · · · ·			•	30 (68)























Date:	
	·















Date: Risk Management Plan The fourth version of the European RMP of rimonabant, is submitted as initially planned 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 () 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. presenting background incidence rates of epidemiology results depression, suicide death and suicide attempts, anxiety, seizures and cardiovascular events in an obese American population. Results from depression among smokers in the 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 () 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: • 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 database. submission of the protocol for assessing the association between nonrecurrent suicide attempts and the use of rimonabant and A new pharmacoepidemiological study • 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

47 (68)

European RMP, updated with a new questionnaire for prescription surveys taking into

protocol for "rimonabant in Clinical Practice", a drug utilization survey in primary care

account the changes in labeling of July 2007.

– submission of an outline for a prescription study



Assessor's comment:		0.11		•
Regarding the synopsis	. The	e synopsis descri	bes the various app	roaches
for a case-control study to as	ssess the risk of suic	ide attempts (SA)) in association with	the use
of rimonabant by using the and controls, exposure and ri	information sy	stem, i.e. definiti ment data valid	on and enrollment o	of cases
Overall, the system see	ems to provide value	nem, adia valido able resources to	perform the study a	maiion. and to
generate meaningful results.	Also, the case-contr	ol methodology,	in the briefly descr.	ibed
aspects, appears adequate for to 3-fold increase of the risk j	r the purpose of the for SA in users of ri	study, yielding t monahant given	in 80 % power to de	etect a 2-
on the prevalence of rimonab	ant use in referents	. There are many	challenges foresee	n in the
conduct of the study, importa	nt ones being chara	cterization of th	e psychiatric disord	er in SA
patients taking rimonabant as patients for SA. One crucial i				
rimonabant froms the effect of	of weight reduction p	per se in these of	bese patients. There	ejjeci oj fore,
detailed information on the th	he index psychiatric	events and on re	elevant comorbidity	will be
important. In summary, the study as des	cerihad in the sumon	gie is broadh, an	downed However a	£.11
detailed protocol for the stud	ly is awaited.	sis is brodaly en	uorsea. However, a	juii ana
-		·		
		· · · · · · · · · · · · · · ·		
	:			
		v		•
	,			





Date: Regarding the RMP The results from the Drug Utilization Study 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 Information System study as described in the synopsis is broadly endorsed. However, a full and detailed protocol for the study is awaited. The protocol-or synopsis for the new pharmacoepidemology study should be provided by the company.





	Date:				
	•				
				·	
		1.			
•					
		·			
				,,,,,,	
					•
			: 1		









	Date:	·			
			:		
	· ·				
	•				
			•		•
					· · ·,
		•			
	. "				-
		÷	*		
				$\delta = 1/2$	
			, -	•	
			-		
					:
					4.
	•				
			•		
		e de la companya de l			
				• .	
					4
		-			
		•			
	•		•		
	•	,			٠
	•				
					v
				. *	
	•				
•			•		-





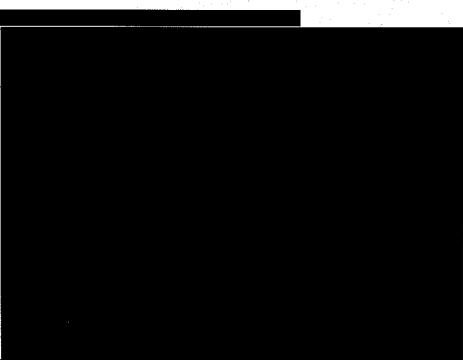














		Date:					
							_
					•		
							,
w					ĺ		
	:				· . · .		
	 · ·		4				
						-	
					- -		
						e Ale Services	
					v v		







63.(68)











