

Mean numbers of deaths and serious adverse drug reactions reported monthly in EudraVigilance, the database of European Medicines Agency for Chronic HCV medications

Name(s)	REBETOL®, COPEGUS®	PEGASYS®	VIRAFERONPEG®	PEGINTRON®	All (peg-IFN)	VICTRELIS®	INCIVO®	SOVALDI®	OLYSIO®	DAKLINZA®	HARVONI®	EXVIERA®	VIEKIRAX®
Active substance	Ribavirin	peginterferon alfa-2a	peginterferon alfa-2b	peginterferon alfa-2b	peg-IFN alfa-2a + alfa-2b	boceprevir	telaprevir	sofosbuvir	simeprevir	daclatasvir	sofosbuvir + ledipasvir	dasabuvir	Ombitasvir / paritaprevir / ritonavir
Therapeutic area	Hepatitis C, Chronic	Hepatitis B, Chronic Hepatitis C, Chronic	Hepatitis C, Chronic	Hepatitis C, Chronic	Hepatitis B, Chronic Hepatitis C, Chronic	Hepatitis C, Chronic	Hepatitis C, Chronic	Hepatitis C, Chronic	Hepatitis C, Chronic	Hepatitis C, Chronic	Hepatitis C, Chronic	Hepatitis C, Chronic	Hepatitis C, Chronic
ATC code	J05AB04	L03AB11	L03AB10	L03AB10	L03AB10 & L03AB11	J05AE12	J05AE11	J05AX15	J05AE14	J05AX14			
Marketing-authorisation holder	Merck Sharp & Dohme Ltd	Roche Registration Limited	Merck Sharp & Dohme Ltd	Merck Sharp & Dohme Ltd		Merck Sharp & Dohme Ltd	Janssen-Cilag International N.V.	Gilead Sciences International Ltd	Janssen-Cilag International N.V.	Bristol-Myers Squibb Pharma EEIG	Gilead Sciences International Ltd	AbbVie Ltd	AbbVie Ltd
Date of issue of marketing authorisation valid throughout the European Union *	07/05/1999	20/06/2002	29/05/2000	25/05/2000		18/07/2011	19/09/2011 Withdrawn 30/04/2015	16/01/2014	14/05/2014	22/08/2014	17/11/2014	15/01/2015	15/01/2015
Usually in combination with:	- peg-IFN - peg-IFN + boceprevir	-ribavirin - ribavirin + other Direct-Acting Antiviral (DAA)	-ribavirin - ribavirin + other DAA	-ribavirin - ribavirin + other DAA	-ribavirin - ribavirin + other DAA	- peg-IFN + ribavirine	- peg-IFN + ribavirine	- peg-IFN + ribavirine - ribavirine	- peg-IFN + ribavirine	- sofosbuvir - sofosbuvir + ribavirine - peg-interféron alfa + ribavirine	-bithérapie - ribavirine	- ombitasvir / paritaprevir/ ritonavir - ombitasvir / paritaprevir/ ritonavir + ribavirin	- dasabuvir - dasabuvir + ribavirin
Treatment duration	24-48 weeks	24-48 weeks	24-48 weeks	24-48 weeks	24-48 weeks	24-44 weeks	12 weeks	12-24 weeks	12-24 weeks	12-24 weeks	12-24 weeks	12-24 weeks	12-24 weeks
Number of months in EudraVigilance (to 05/2015) *	162,0	155,3	162,0	162,0		46,4	43,4	16,5	12,5	9,3	6,4	4,5	4,5
Mean number of deaths by month in EudraVigilance	13,8	9,1	0,7	3,4	13,2	7,2	4,5	13,4	4,9	3,3	7,3	1,1	1,1
Mean number of serious ADR by month in EudraVigilance	166,0	103,0	4,3	43,4	150,6	51,9	65,9	98,1	42,0	46,9	59,4	9,3	9,5
% Death per Serious ADR	8,3%	8,8%	16,9%	7,7%	8,7%	13,8%	6,9%	13,7%	11,8%	7,1%	12,3%	11,9%	11,6%

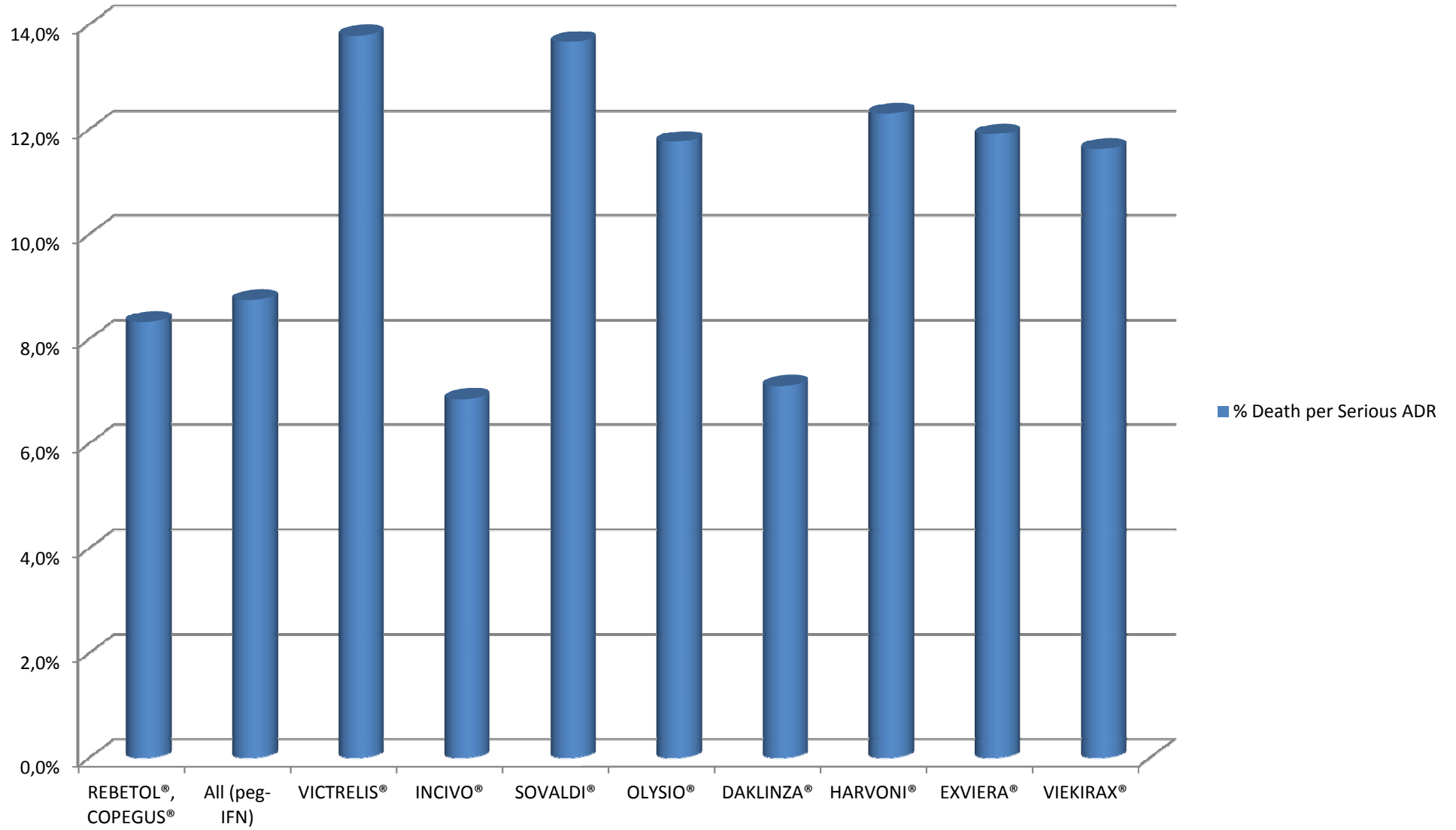
(*)The first operating version of Eudravigilance was launched in December 2001

[Data Source :
http://www.adrreports.eu/en/data_source.html](http://www.adrreports.eu/en/data_source.html)

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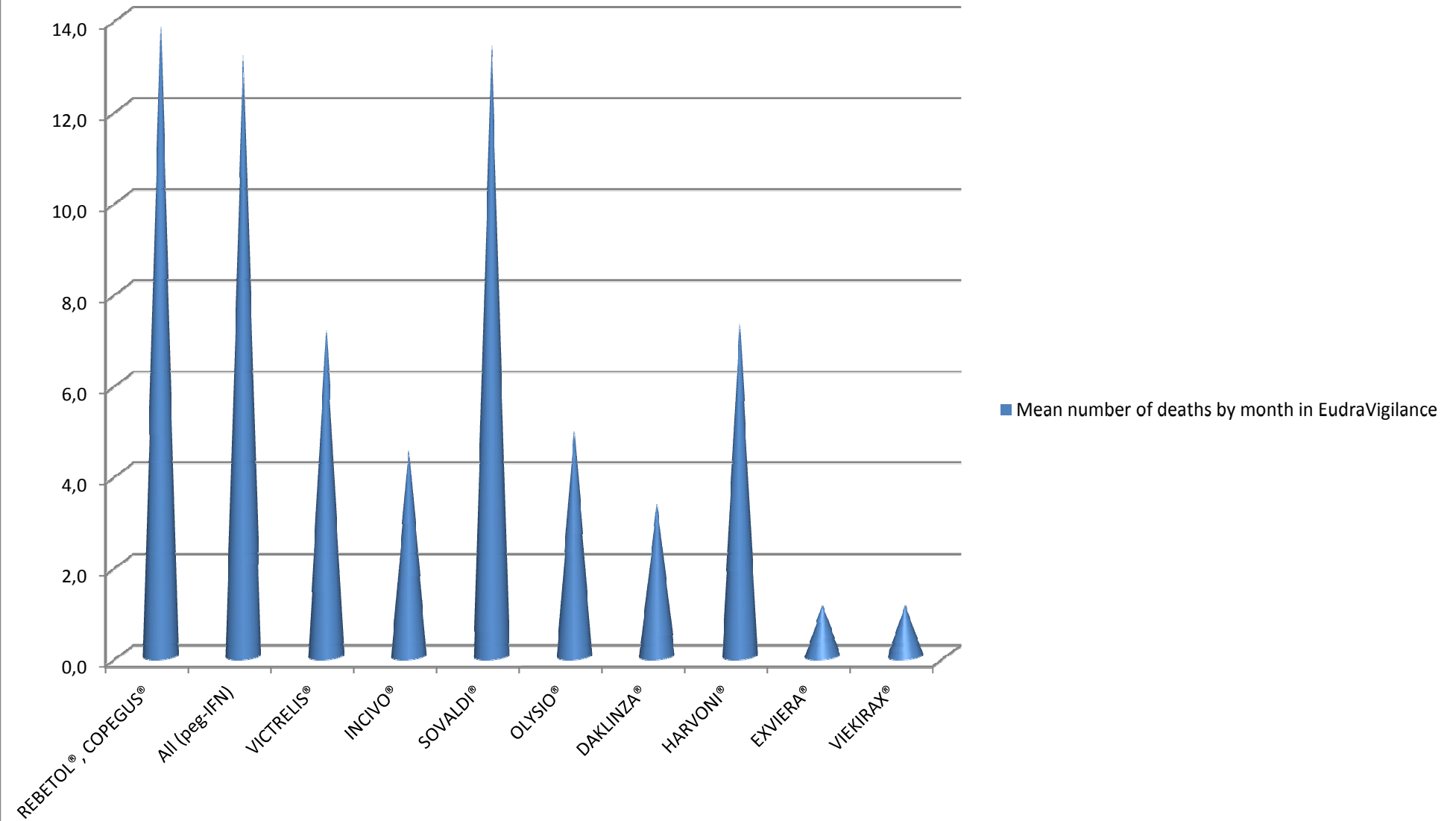
% Death per Serious ADR

(Data source: Eudravigilance up-to 05/2015)



Mean number of deaths monthly reported in EudraVigilance

(Data source: Eudravigilance up-to 05/2015)



Mean number of serious ADR monthly reported in EudraVigilance

(Data source: Eudravigilance up-to 05/2015)

