



Reorienting European policy on medicines for human use

For a balanced legislation

Vote on REGULATION

Article	Amendment	Medicines in Europe Forum	
		position	comment
recital 8	36	0	
recital 12	1	+	
recital 13	2	+	ATV is key for rational drug choices
recital 14a	3	-	first part acceptable, but second one (incentives) is controversial
recital 14b	4	+	Europe must help developing countries
recital 16a	5	+	
recital 19a	37	+	public interest requires public funding
art 3, par 3, pt b	38,39,40	+	will suppress a potential barrier for generics
art 3, par 5	6	+	all new drugs should follow central procedure
art 5, par 3	7	+	disagreements should be dealt transparently
art 6, par 1	41	+	ethics cross borders
art 6, par 3, subpar 1a, b, c	42	+	proper scientific assessment needs time
art 13 par 3a	43,44	+	patients reporting is needed



+ = strongly supported by MEF
- = opposed by MEF

+ = supported by MEF
0 = no opinion, or indifferent



Vote on REGULATION

art 14, par 2, subpar 1	8	+	better choice: AM 45
art 14, par 2	45	+	practical drug information is comparative
art 14, par 2, subpar 2a	46	+	up-dated information is essential
art 14, par 7	9	+	transparency is due to all European citizens
art 14, par 11	10	+	to guarantee access to drugs at reasonable price
art 14, par 11	47	-	would delay generics availability
art 17	11	+	data falsification should be prosecuted
art 20, par 7	12	+	transparency is due to all European citizens
art 22, par 1	13	+	transparency is due to all European citizens
art 24, par 3, subpar 2	14	+	relevant starting point is marketing
art 24, par 5a	48	+	patients may need to report personally
art 26, par 3	15	+	transparency is due to all European citizens
art 30, par 3	16	0	
art 39, par 2, subpar 1	17	0	
art 39, par 2	49	0	
art 39, par 2, subpar 2	50,51	0	



+ = strongly supported by MEF
- = opposed by MEF

+ = supported by MEF
0 = no opinion, or indifferent



Vote on REGULATION

art 39, par 2, subpar 2a	52	0	
art 45, par 7	18	0	
art 47, par 1	19	+	transparency is due to all European citizens
art 56, par 1a	20	0	
art 56, par 2	21	0	
art 57, par 1, subpar 2, pt b	22	+	rational use of drugs requires clear and adapted information
art 57, par 1(k)	23	+	better choice: AM 53
art 57, par 1, subpar 2, pt k	53	+	reliable information needs public funding
art 57, par 1(pa)	24	+	Europe must help developing countries
art 57, par 2	25	+	database should be comprehensive
art 57, par 2, subpar 1a	26	+	clinical trials are key drug information
art 60	27	+	ATV is key for rational drug choices
art 61, par 1	28	0	
art 62, par 1, subpar 1	29	0	
art 62, par 2, subpar 1	30	0	
art 64, par 3	31	+	EMA annual report should be comprehensive
art 65, par 1	32	-	better choice: AM 57
art 58, par 1, subpar 1	54	-	better choice: AM 57; consultative only is unacceptable



+ = strongly supported by MEF
- = opposed by MEF

+ = supported by MEF
0 = no opinion, or indifferent



Vote on REGULATION

art 65, par 1	55	+	better choice: AM 57
art 65, par 1	56	-	better choice: AM 57
art 65, par 1	57	+	involves every civil society stakeholder
art 67, par 4	58	+	public interest requires public funding
art 67, par 5	59	+	
art 73, subpar 1a	60	+	effective transparency is due to all European citizens
art 78, par 2	61	+	patients and professionals deserve attention
art 83, par 1a	62	+	decision should not be bureaucratic
art 83, par 3	63	+	access should be guaranteed
art 83, par 4	64	+	programs should involve health authorities and have appropriate scale
art 83, par 6a	65	-	public interest requires adequate public funding
art 83, par 7a	33	-	public interest requires adequate public funding
annex, par 3	34	+	all new drugs should soon follow clear and transparent central procedure
annex, par 3, subpar 1	66	0	
annex, par 3a	35	0	

+ = strongly supported by MEF
- = opposed by MEF

+ = supported by MEF
0 = no opinion, or indifferent



Reorienting European policy on medicines for human use

For a balanced legislation

Vote on DIRECTIVE

Article	Amendment	Medicines in Europe Forum	
		position	comment
recital 4	15	+	public health before trade
recital 8	16	+	
recital 16a	17	-	risk of bias from Commission
recital 16a	18	+	
recital 18	19	+	pharmacovigilance has no borders
recital 19a	20	+	Europe should help developing countries
art 1, par 2 a and b	21	-	no need to change definition, just to favour medical devices industry
art 1, par 2, pt b	1	-	no need to change definition, just to favour medical devices industry
art 1, pt 28, 28a	22	+	
art 2, par 2	23to26	-	even if common position not optimum
art 2, par 2	27	-	even if common position not optimum
art 2, par 2	28,30	-	even if common position not optimum
art 2, par 2	29	-	even if common position not optimum
art 3, par 7a	31	-	even if common position not optimum
art 5, par 1a	32	+	Europe should offer compassionate use
art 6, par 1a	33	0	

+ = strongly supported by MEF
- = opposed by MEF

+ = supported by MEF
0 = no opinion, or indifferent





Vote on DIRECTIVE

art 8, par 3, pt c (a)	34	+	
art 8, par 3, pt i	35	+	
art 8, par 3, i-3	36	+	better choice: AM 37
art 8, par 3, i-3	37	+	comparative information is needed
art 8, par 3, i-3-a	38	+	
art 8, par 3, pt 1b	39	+	better choice: AM 41
art 8, par 3, pt i (c)	40	+	long term data are lacking
art 8, par 3, i (c)	41	+	ethics cross borders
art 8, par 3, i (a)	42	+	long term data are lacking
art 10, par 2	2	-	would delay generics availability
art 10, par 2 (a)	3	-	data protection already the highest at world-wide level
art 10, par 1	43	-	would delay generics availability
art 10, par 1, subpar 2	44	+	to guarantee access to drugs at reasonable price
art 10, par 1, subpar 1	45	-	would delay generic availability
art 10, par 1, subpar 1 (a)	46	+	would help acceding countries
art 10, par 2, pt b	4	-	protectionist barrier against generics
art 10, par 2, b	47	-	no need to change definition
art 10, par 2 (b)	48	-	no need to change definition
art 10, par 2 (b)	49	-	no need to change definition
art 10, par 2 b	50	-	no need to change definition
art 10, par 2 (b)	51	-	no need to change definition

+ = strongly supported by MEF
- = opposed by MEF

+ = supported by MEF
0 = no opinion, or indifferent





Vote on DIRECTIVE

art 10, par 4	5	-	highly protectionist for the most expensive drugs
art 10, par 4	52	-	protectionist for the most expensive drugs
art 10, par 4	53	+	or AM 54
art 10, par 4	54	+	or AM 53
art 10, par 4 (a)	55,56,58	-	should be more precise: only for a real therapeutic advance for patients
art 10, par 4 (a)	57	+	Europe should help developing countries
art 10, par 5	59	-	better choice: AM 61
art 10, par 5	60	-	better choice: AM 61
art 10, par 5	61	+	
art 10 (a)	62	+	to guarantee access to drugs
art 10 c (a)	63	+	
art 10 c (a)	64	+	Europe should help developing countries
art 13, par 1	65	0	
art 14, par 1, 1	66 to 68	0	
art 14, par 1, 3	69,70	0	
art 16, par 2	71,72	0	
art 17, par 1	6	-	150 days too short; even with 80 days for assessment report
art 21, par 4	73	+	each indication must be substantiated



+ = strongly supported by MEF
- = opposed by MEF

+ = supported by MEF
0 = no opinion, or indifferent



Vote on DIRECTIVE

art 22	74	+	transparency is due to all European citizens
art 23, par 3	75	+	all data should be analysed
art 24, par 2	76	+	comparative information is needed
art 26, par 2 (a)	77	+	data falsification should be prosecuted
art 30, par 1	78	+	disagreements require centralised expertise
art 54, a	79	+	better choice: AM 80
art 54, pt a	80	+	INN is part of transparency
art 54, pt a	81	+	better choice: AM 80
art 54, pt (e)	7	+	space for practical and personal information
art 54, j)	82	+	unused drugs should be properly destroyed
art 55, par 3 a)	83	+	better choice: AM 85
art 55, par 3 (b)	84	+	better choice: AM 85
art 55 (a)	85	+	patients need clear information
art 55 ter	86	+	need for reliable and comparative information
art 56	87	+	better choice: AM 85
art 59, par 1 a)	88	+	INN is part of transparency
art 59, par 1 d) (a)	89,90,95	+	patients may need to report personally
art 59, par 1 (e)	91	+	patients may need to report personally

+ = strongly supported by MEF
- = opposed by MEF

+ = supported by MEF
0 = no opinion, or indifferent





Vote on DIRECTIVE

art 59, par 1 (e)	92,94	+	patients may need to report personally. Or AM 91
art 59, par 1 a) i	93	+	INN is part of transparency
art 69, par 1, 11	96	0	
art 69, par 1, 11	97	0	
art 74 a	8	-	highly protectionist; higher cost for patients
art 81, par 2	98	+	public health protection. Or AM 99
art 81, par 2	99	+	public health protection. Or AM 98
art 81, par 2a, b and c	100	0	
art 86, par 1	9	-	source of confusion
art 87c, par 2	101	-	source of confusion
art 88, par 6a	10	-	risk of bias from Commission
art 88, par 6 (a)	102	-	risk of bias from Commission
art 88, par 6 (a)	103	-	risk of bias from Commission
art 88, par 6 (a)	104,105	+	national authorities should provide objective information
art 88, par 6 (a)	106	0	risk of bias from Commission
art 89, par 1 b)	107	+	INN is part of transparency. Or AM 108
art 89, par 1 b)	108	+	INN is part of transparency. Or AM 107
art 89, par 1 b), 3	109	+	drugs are not commodities
art 89, par 2	110	+	INN is part of transparency



+ = strongly supported by MEF
- = opposed by MEF

+ = supported by MEF
0 = no opinion, or indifferent



Vote on DIRECTIVE

art 91, par 2	111	+	INN is part of transparency
art 94, par 1	112	+	bribery must be prosecuted
art 94, par 2	113	+	bribery must be prosecuted
art 98, par 3	114	0	
art 101, par 2	115,116	+	
art 101, par 2 (a)	117	+	
art 102 a	11	+	public interest requires public funding
art 104, par 6	118	+	
art 104, par 6	119	+	transparency is due to all European citizens
art 107, par 2 (a)	120	+	transparency is due to all European citizens
art 111, par 1, subpar 1	12	+	
art 111, par 1, pt b	13	+	
art 126 a, par 1	121	0	
art 126 a, par 2	122	0	
art 126 a, par 4	123	0	
art 126 a, par 4	124	+	transparency is due to all European citizens
art 126 ter	125	+	transparency is due to all European citizens
art 127b	14	+	unused drugs should be properly destroyed

+ = strongly supported by MEF
- = opposed by MEF

+ = supported by MEF
0 = no opinion, or indifferent