

19 December 2013
EMA/774164/2013

Overview of invented names reviewed in November 2013 by the Name Review Group (NRG)

Adopted at the CHMP meeting of 16 – 19 December 2013

	NRG meeting 30 Jan 2013		NRG meeting 10 April 2013		NRG meeting 11 June 2013		NRG meeting 4 July 2013		NRG meeting 02 Oct 2013		NRG meeting 14 Nov 2013		2013	
	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected
Proposed invented names	42	33	44	38	33	35	41	29	67	39	57	51	284	225
Justification for retention of invented name *	-	2	2	2	-	2	1	1	3	-	5	3	11	10

*In case of objections to the proposed invented name(s), the applicant may justify the retention of the proposed invented name using the relevant justification form available on the EMA website.

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Objections	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected
Total number of objections raised	56	54	80	40	67	78	50	31	64	54	77	65	394	322
Criterion - Safety concerns														
Similarity with other Invented name	49	39	63	34	59	75	35	22	56	49	70	58	332	277
Conveys misleading therapeutic/pharmaceutical connotations		2		1	1		1	3			1		3	6
Misleading with respect to composition		1	1				2				1		4	1
Criterion - INN concerns														
Similarity with INN		8	1	1	1		5	3	1	3	1		9	15
Inclusion of INN stem	3		1	2		1			1				5	3
Criterion - Other public health concerns														
Unacceptable qualifiers	1	1								1	1		2	2
Conveys a promotional message	1	3				1		1			1	2	2	7
Appears offensive or has a bad connotation	2		1				3		1		1		8	
Similarity between name of individual active substance and fixed combinations and/or between fixed combinations			13	2	3	1	3				1		20	3
Similarity between name of prodrug and related active substance														
Others					3		1	2	5	1		5	9	8

See Guideline on the Acceptability of Names for Human Medicinal Products Processed through the Centralised Procedure (CPMP/328/98 Rev. 5) for detailed explanations of criteria used.