

22 October 2015 EMA/695525/2015 Human Medicines Evaluation Division

Overview of (invented) names reviewed in September 2015 by the Name Review Group (NRG)

Adopted at the CHMP meeting of 19-22 October 2015

	NRG meeting 28 Jan 2015		NRG meeting 25 Mar 2015		NRG meeting 20 May 2015		NRG meeting 01 Jul 2015		NRG meeting 30 Sep 2015		NRG meeting 25 Nov 2015		2015	
Proposed (invented) names	Accepted 26	Rejected 22	Accepted 22	Rejected 27	Accepted 19	Rejected 39	Accepted 21	Rejected 25	Accepted 35	Rejected 37	Accepted	Rejected	Accepted	Rejected
Justification for retention of (invented) name *	4	2	3	1	1	1	0	2	2	5				

^{*}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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	Accepted	Rejected	Accepted	Rejected										
Total number of objections raised	45	25	53	53	69	53	47	17	76	30				
Criterion - Safety concerns														
Similarity with other (invented) name	25	23	34	49	53	48	39	14	61	24				
Conveys misleading therapeutic/pharmaceutical connotations	4	0	4	0	0	0	1	0	0	0				
Misleading with respect to composition	7	1	3	2	0	0	0	1	0	1				
Criterion - INN concerns														
Similarity with INN	0	1	1	0	4	2	2	0	5	1				
Inclusion of INN stem	0	0	2	1	1	0	1	0	0	2				
Criterion - Other public health concerns														
Unacceptable qualifiers	6	0	4	0	1	0	0	0	1	0				
Conveys a promotional message	1	0	2	1	1	1	1	1	2	1				
Appears offensive or has an inappropriate connotation	1	0	3	0	7	0	2	0	1	1				
Similarity between name of individual active substance and fixed combinations and/or between fixed combinations	0	0	0	0	0	0	0	0	2	0				
Similarity between name of prodrug and related active substance	0	0	0	0	0	0	0	0	0	0				
Others	1	0	0	0	2	2	1	1	4	0				

See Guideline on the <u>Acceptability of Names for Human Medicinal Products Processed through the Centralised Procedure (EMA/CHMP/287710/2014)</u> for detailed explanations of criteria used.