

23 June 2016 EMA/435524/2016 Human Medicines Evaluation Division

Overview of (invented) names reviewed in June 2016 by the Name Review Group (NRG)

Adopted at the CHMP meeting of 20-23 June 2016

	NRG m	NRG meeting 03 Feb 2016		Ŭ		NRG meeting 01 June 2016				NRG meeting 21 Sep 2016		NRG meeting 23 Nov 2016		2016	
	03 Feb														
Proposed (invented) names	Accepted 27	Rejected 35	Accepted 48	Rejected 52	Accepted 40	Rejected 42	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	
Justification for retention of (invented) name *	0	4	1	6	1	1									

*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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	NRG meeting 03 Feb 2016		NRG meeting 06 April 2016		NRG meeting 01 June 2016		NRG meeting 06 Jul 2016		NRG meeting 21 Sep 2016		NRG meeting 23 Nov 2016		2016	
	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected
Total number of objections raised	72	39	113	90	110	77								
Criterion - Safety concerns														
Similarity with other (invented) name	62	33	108	86	96	71								
Conveys misleading therapeutic/pharmaceutical connotations	0	0	0	0	1	0								
Misleading with respect to composition	1	0	1	0	0	0								
Criterion - INN concerns														
Similarity with INN	3	3	2	3	4	2								
Inclusion of INN stem	0	0	0	1	1	0								
Criterion - Other public health concerns														
Unacceptable qualifiers	1	0	0	0	2	0								
Conveys a promotional message	1	0	1	0	1	3								
Appears offensive or has an inappropriate connotation	1	0	0	0	2	1								
Similarity between name of individual active substance and fixed combinations and/or between fixed combinations	0	0	0	0	0	0								
Similarity between name of prodrug and related active substance	0	0	0	0	0	0								
Others	3	3	1	0	3	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.