

10 October 2017 EMA/820554/2017 Human Medicines Evaluation Division

## Overview of (invented) names reviewed in November 2017 by the Name Review Group (NRG)

Adopted at the CHMP meeting of 11-14 December 2017

	NRG meeting 01 Feb 2017		NRG meeting 29 March 2017		NRG meeting 31 May 2017		NRG meeting 06 Jul 2017		NRG meeting 20 Sep 2017		NRG meeting 22 Nov 2017	
Proposed (invented) names	Accepted 44	Rejected 26	Accepted 41	Rejected 44	Accepted 41	Rejected 30	Accepted -	Rejected -	Accepted 56	Rejected 55	Accepted 62	Rejected 48
Justification for retention of (invented) name *	2	3	1	6	0	1	-	-	2	7	4	4

<sup>\*</sup>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	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected
Total number of objections raised	54	91	87	157	62	120	-	-	111	99	89	169
Criterion - Safety concerns												
Similarity with other (invented) name	45	82	80	149	59	106	-	-	101	85	74	160
Conveys misleading therapeutic/pharmaceutical connotations	1	0	0	1	0	5	-	-	0	0	2	1
Misleading with respect to composition	2	0	0	0	0	1	-	-	0	2	2	1
Criterion - INN concerns												
Similarity with INN	4	5	3	2	1	6	-	-	1	6	4	1
Inclusion of INN stem	0	3	2	1	0	0	-	-	2	2	-	-
Criterion - Other public health concerns												
Unacceptable qualifiers	1	0	0	0	0	0	-	-	0	0	2	1
Conveys a promotional message	1	0	1	0	2	1	-	-	2	3	0	3
Appears offensive or has an inappropriate connotation	0	0	1	2	0	1	-	-	3	1	2	0
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	-	-
Others	0	1	0	2	0	0	-	-	2	0	1	2

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.