

13 December 2018 EMA/863497/2018 Human Medicines Evaluation Division

Overview of (invented) names reviewed in November 2018 by the Name Review Group (NRG)

Adopted at the CHMP meeting of 10-13 December 2018

	NRG meeting 21 Feb 2018		NRG meeting 28 May 2018		NRG meeting 26 Sep 2018		NRG meeting 22 Nov 2018		2018	
	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected
Proposed (invented) names*	50	39	60	58	68	57	58	51	236	205
Justification for retention of (invented) name **	2	3	1	2	1	6	2	3	6	14

^{*}Includes invented names, INN+MAH/TM and re-use applications.



^{**}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
Total number of objections raised	70	109	108	148	124	140	137	161	439	558
Criterion - Safety concerns										
Similarity with other (invented) name	59	97	93	126	103	123	127	136	382	482
Conveys misleading therapeutic/pharmaceutical connotations	0	0	0	7	5	0	2	1	7	8
Misleading with respect to composition	0	0	1	1	2	0	0	0	3	1
Criterion - INN concerns										
Similarity with INN	5	4	3	4	2	6	1	4	11	18
Inclusion of INN stem	1	1	2	0	1	1	1	0	5	2
Criterion - Other public health concerns										
Unacceptable qualifiers	1	0	2	1	0	1	0	1	3	3
Conveys a promotional message	0	3	1	6	5	4	4	1	10	14
Appears offensive or has an inappropriate connotation	1	2	2	0	4	1	1	0	8	3
Similarity between name of individual active substance and fixed combinations and/or between fixed combinations	3	0	0	2	0	0	0	0	3	2
Similarity between name of prodrug and related active substance	0	0	0	0	0	0	0	0	0	0
Others	0	2	4	1	2	4	2	3	8	10

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.