

18 October 2018 EMA/727739/2018 Human Medicines Evaluation Division

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

Adopted at the CHMP meeting of 15-18 October 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	-	-	178	154
Justification for retention of (invented) name **	2	3	1	2	1	6	-	-	4	11

<sup>\*</sup>Includes invented names, INN+MAH/TM and re-use applications.



<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.

	NRG meeting		NRG meeting 28 May 2018		NRG meeting 26 Sep 2018		NRG meeting 22 Nov 2018		2018	
										Data da d
Total number of objections raised	Accepted 70	Rejected 109	Accepted 108	Rejected 148	Accepted 124	Rejected 140	Accepted -	Rejected -	Accepted 302	Rejected 397
Criterion - Safety concerns	, 0	103	100	1.0		110			302	
Similarity with other (invented) name	59	97	93	126	103	123	_	-	255	346
Conveys misleading therapeutic/pharmaceutical connotations	0	0	0	7	5	0	-	-	5	7
Misleading with respect to composition	0	0	1	1	2	0	-	-	3	1
Criterion - INN concerns										
Similarity with INN	5	4	3	4	2	6	-	-	10	14
Inclusion of INN stem	1	1	2	0	1	1	-	-	4	2
Criterion - Other public health concerns										
Unacceptable qualifiers	1	0	2	1	0	1	-	-	3	2
Conveys a promotional message	0	3	1	6	5	4	-	-	6	13
Appears offensive or has an inappropriate connotation	1	2	2	0	4	1	-	-	7	3
Similarity between name of individual active substance and fixed combinations and/or between fixed combinations	3	0	0	2	0	0	-	-	3	2
Similarity between name of prodrug and related active substance	0	0	0	0	0	0	-	-	0	0
Others	0	2	4	1	2	4	-	-	6	7

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.