

10 December 2019 EMA/673317/2019 Human Medicines Evaluation Division

## Overview of (invented) names reviewed in November 2019 by the Name Review Group (NRG)

Adopted at the CHMP meeting of 09-12 December 2019

	NRG meeting 26-27 Feb 2019		NRG meeting 21-22 May 2019		NRG meeting 18 Sep 2019		NRG meeting 22 Nov 2019		2019	
	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected
Proposed (invented) names*	56	62	58	56	51	60	51	67	216	245
Justification for retention of (invented) name **	6	7	3	8	3	5	0	8	12	28

<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 26-27 Feb 2019		NRG meeting 21-22 May 2019		NRG meeting 17-18 Sep 2019		NRG meeting 12-13 Nov 2019		2019	
	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected
Total number of objections raised	139	182	109	141	150	191	186	194	584	708
Criterion - Safety concerns										
Similarity with other (invented) name	122	147	89	119	131	162	152	152	494	580
Conveys misleading therapeutic/pharmaceutical connotations	1	3	0	0	4	3	4	0	9	6
Misleading with respect to composition	0	0	0	1	0	0	4	0	4	1
Criterion - INN concerns										
Similarity with INN	5	5	5	2	9	1	2	2	21	10
Inclusion of INN stem	0	0	3	4	2	1	1	1	6	6
Criterion - Other public health concerns										
Unacceptable qualifiers	0	0	0	0	0	0	2	0	2	0
Conveys a promotional message	5	2	5	2	2	2	5	3	17	9
Appears offensive or has an inappropriate connotation	0	0	3	0	0	0	7	0	10	0
Similarity between name of individual active substance and fixed combinations and/or between fixed combinations	0	0	0	0	0	0	0	0	0	0
Similarity between name of prodrug and related active substance	0	0	0	0	0	0	0	0	0	0
Others	6	25	3	13	2	22	9	36	20	96

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.