

13 October 2021 EMA/586201/2021 Human Medicines Division

## Overview of (invented) names reviewed in September 2021 by the Name Review Group (NRG)

Adopted at the CHMP meeting of 11-14 October 2021

		NRG meeting 16-17 Feb 2021		NRG meeting 20-21 Apr 2021		NRG meeting 26-27 May 2021		NRG meeting 29-30 Jun 2021		NRG meeting 16-17 Sep 2021		NRG meeting 09-10 Nov 2021		2021 total	
	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	
Proposed (invented) names*	73	33	33	36	24	31	38	34	64	30	0	0	232	164	
Justification for retention of (invented) name **	3	3	2	7	2	0	1	6	3	8	0	0	11	24	

<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 16-17 Feb 2021		NRG meeting 20-21 Apr 2021		NRG meeting 26-27 May 2021		NRG meeting 29-30 Jun 2021		NRG meeting 16-17 Sep 2021		NRG meeting  09-10 Nov 2021		2021 total	
	Accepted	Rejected	Accepted				Accepted	Rejected			Accepted	Rejected	Accepted	Rejected
Total number of objections raised	69	173	75	92	61	78	59	92	51	155	0	0	315	590
				Crite	rion - Saf	ety conc	erns							
Similarity with other (invented) name	46	119	61	68	45	55	37	70	36	114	0	0	225	426
Conveys misleading therapeutic/pharmaceutical connotations	1	0	1	1	0	0	2	2	1	3	0	0	5	6
Misleading with respect to composition	1	0	0	0	0	0	1	4	0	2	0	0	2	5
				Crite	erion - IN	IN conce	rns							
Similarity with INN	12	8	1	3	2	6	2	1	5	3	0	0	22	21
Inclusion of INN stem	0	0	0	1	0	1	0	0	0	0	0	0	0	2
			Cri	iterion - 0	Other pub	lic healtl	h concer	ns						
Unacceptable qualifiers	2	0	2	0	0	2	8	0	4	0	0	0	16	2
Conveys a promotional message	3	4	3	1	2	5	8	2	4	5	0	0	20	17
Appears offensive or has an inappropriate connotation	1	2	2	0	5	1	0	1	0	0	0	0	8	4
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	0	0	0	0
Similarity between name of prodrug and related active substance	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Others	3	40	6	22	7	8	1	12	1	31	0	0	18	113

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.