



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 July 2020
EMA/356004/2020
Human Medicines Division

Overview of (invented) names reviewed in June/July 2020 by the Name Review Group (NRG)

Adopted at the CHMP meeting of 20-23 July 2020

| | NRG meeting 25-26 Feb 2020 | | NRG meeting 23 Apr 2020 | | NRG meeting 02-03 June 2020 | | NRG meeting 30 Jun-01 Jul 2020 | | NRG meeting 15-16 Sep 2020 | | NRG meeting 24-25 Nov 2020 | | 2020 total | |
|---|-------------------------------|----------|----------------------------|----------|--------------------------------|----------|-----------------------------------|----------|-------------------------------|----------|-------------------------------|----------|------------|----------|
| | Accepted | Rejected | Accepted | Rejected | Accepted | Rejected | Accepted | Rejected | Accepted | Rejected | Accepted | Rejected | Accepted | Rejected |
| Proposed (invented) names* | 44 | 69 | 19 | 33 | 42 | 31 | 49 | 28 | - | - | - | - | 154 | 161 |
| Justification for retention of (invented) name ** | 6 | 11 | 0 | 0 | 5 | 9 | 0 | 0 | - | - | - | - | 11 | 20 |

*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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| | NRG meeting 26-27 Feb 2019 | | NRG meeting 23 Apr 2020 | | NRG meeting 02-03 June 2020 | | NRG meeting 30 Jun-01 Jul 2020 | | NRG meeting 18 Sep 2020 | | NRG meeting 22 Nov 2020 | | 2020 | |
|---|-------------------------------|----------|----------------------------|----------|-----------------------------------|----------|--------------------------------------|----------|----------------------------|----------|----------------------------|----------|----------|----------|
| | Accepted | Rejected | Accepted | Rejected | Accepted | Rejected | Accepted | Rejected | Accepted | Rejected | Accepted | Rejected | Accepted | Rejected |
| Total number of objections raised | 141 | 213 | 96 | 120 | 58 | 109 | 53 | 126 | - | - | - | - | 348 | 568 |
| Criterion - Safety concerns | | | | | | | | | | | | | | |
| Similarity with other (invented) name | 115 | 154 | 81 | 85 | 49 | 88 | 49 | 89 | - | - | - | - | 294 | 216 |
| Conveys misleading therapeutic/pharmaceutical connotations | 2 | 6 | 1 | 2 | 1 | 0 | 1 | 2 | - | - | - | - | 5 | 10 |
| Misleading with respect to composition | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | - | - | - | - | 0 | 0 |
| Criterion - INN concerns | | | | | | | | | | | | | | |
| Similarity with INN | 7 | 1 | 8 | 4 | 3 | 0 | 0 | 0 | - | - | - | - | 18 | 5 |
| Inclusion of INN stem | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | - | - | - | - | 2 | 1 |
| Criterion - Other public health concerns | | | | | | | | | | | | | | |
| Unacceptable qualifiers | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | - | - | - | - | 0 | 0 |
| Conveys a promotional message | 4 | 5 | 2 | 4 | 2 | 2 | 2 | 4 | - | - | - | - | 10 | 15 |
| Appears offensive or has an inappropriate connotation | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | - | - | - | - | 1 | 1 |
| 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 | 11 | 46 | 3 | 25 | 3 | 19 | 1 | 30 | - | - | - | - | 18 | 120 |

See *Guideline on the [Acceptability of Names for Human Medicinal Products Processed through the Centralised Procedure \(EMA/CHMP/287710/2014\)](#)* for detailed explanations of criteria used.