
Joint EMEA (NRG)/EFPIA Workshop

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Guideline on acceptability of invented names

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Guideline

Guideline states

- **The use of short qualifiers which do not carry established and relevant meaning in all Member States (“MS”) is unacceptable (section 2.3.1)**
- **IV; IM; and SC may be acceptable suffixes to distinguish routes of administration (section 2.3.1) provided appropriate justification is provided**
- **The invented name should not convey any promotional message with respect to the use of the product e.g. “Plus” (section 2.3.2)**



Qualifiers/Suffixes

The use of short qualifiers which do not carry established and relevant meaning in all MS is unacceptable (section 2.3.1)

IV; IM; and SC may be acceptable suffixes to distinguish route of administration (section 2.3.1) provided appropriate justification is provided

- Under what criteria will the industry be able to determine what is regarded as an established and relevant meaning in each MS?**
- Is this a scientific or linguistic issue?**

Qualifiers/Suffixes (con't)

- Are standard terms only those used by the European Directorate for the Quality of Medicines?
- What is regarded as appropriate justification for the use of the suffixes IV; IM and SC?
- Suffixes may also be appropriate to distinguish not just the route of administration e.g. strength, combination, formulation

If not acceptable in a MS, the possibility for a variation to the qualifier/suffix should be considered

Promotional Claim (Invented Name)

The invented name should not convey any promotional message with respect to the use of the product

- Official statistics from EMEA cite ~15% of proposed invented names are rejected as “promotional”
- Further clarification on the *principles* of what constitutes a “promotional” invented name is appreciated in order for industry to better apply this rule within the CP

Promotional Claim (Suffixes)

The invented name should not convey any promotional message with respect to the use of the product e.g. “Plus” (section 2.3.2)

- **“Plus” can in some instances be used to indicate a combination and is therefore not as such seen as a promotional message**
- **What about terms like “mite”; “forte”; “acute”, “CR”**
- **Numerous examples of national licenses with the above terms are available without impacting the safety of the patients**

Conclusion

Further guidance is sought by industry to the interpretation and use of the Guideline

The possibility for local variations/derogations in the invented name and their suffixes should be allowed