# EMEA-EFPIA Info Day

# The EMEA policy on Invented names

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**Chair of NRG**

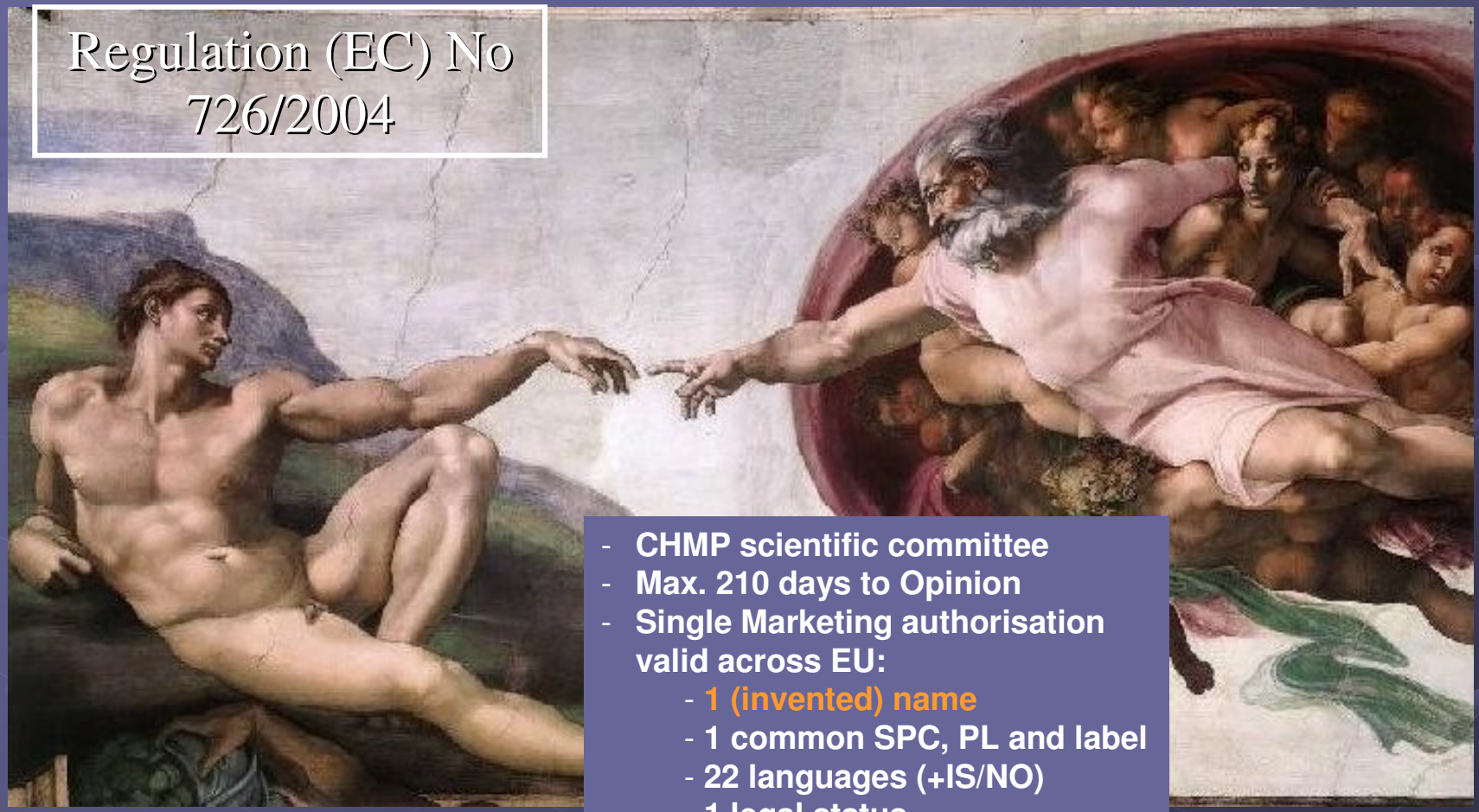
**Regulatory Affairs Administrator**

**EMEA**

**London – 24 February 2009**

# Creation of 'Single name' concept…

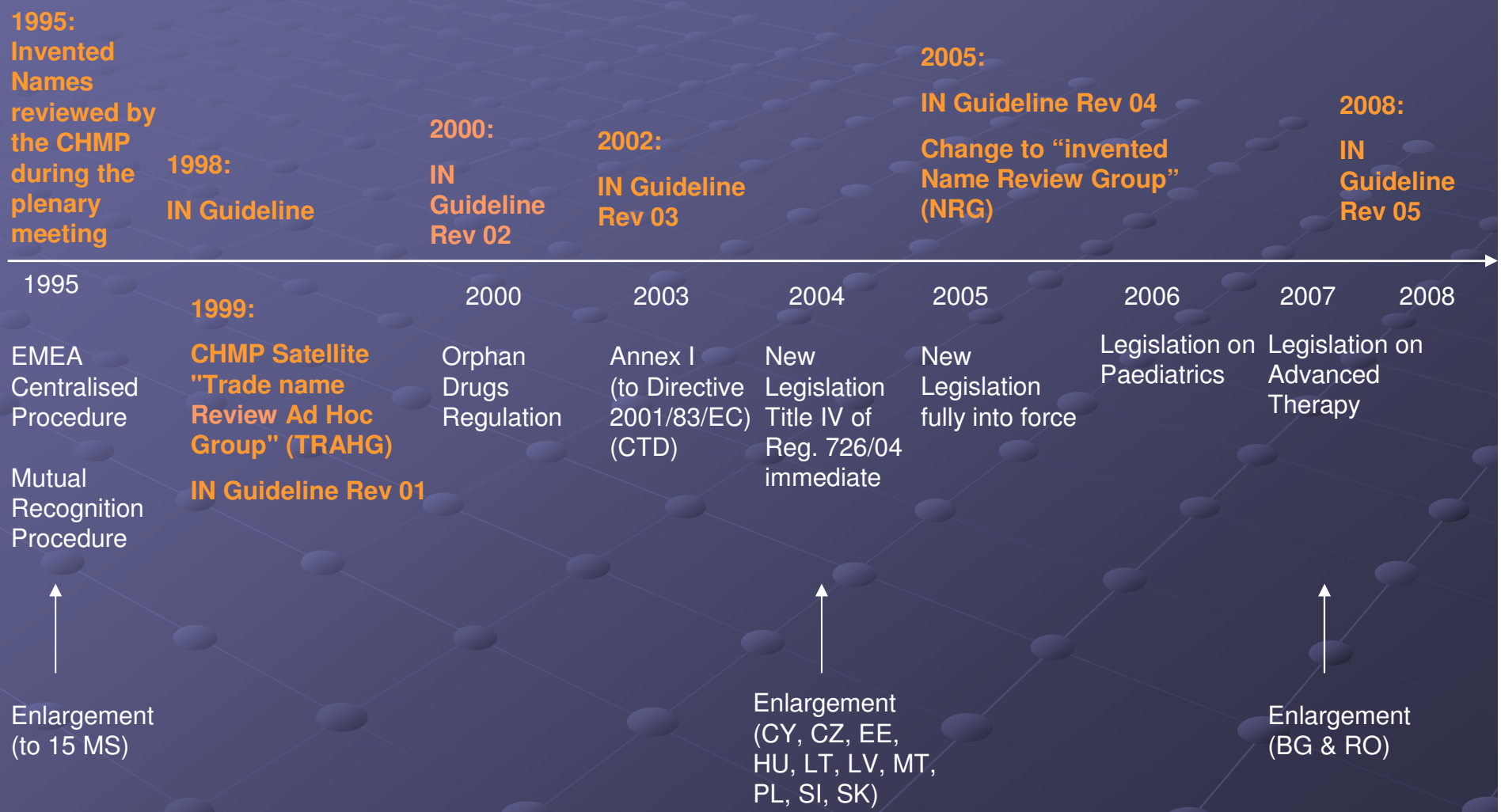
Regulation (EC) No 726/2004



- CHMP scientific committee
- Max. 210 days to Opinion
- Single Marketing authorisation valid across EU:
  - 1 (invented) name
  - 1 common SPC, PL and label
  - 22 languages (+IS/NO)
  - 1 legal status

- 27 Member States
- Access to ~ 495 million users

# The European Regulatory Environment changed dramatically since 1995 …



# Objective of NRG review

*"Guideline on acceptability of names for human medicinal products processed through the Centralised procedure"*

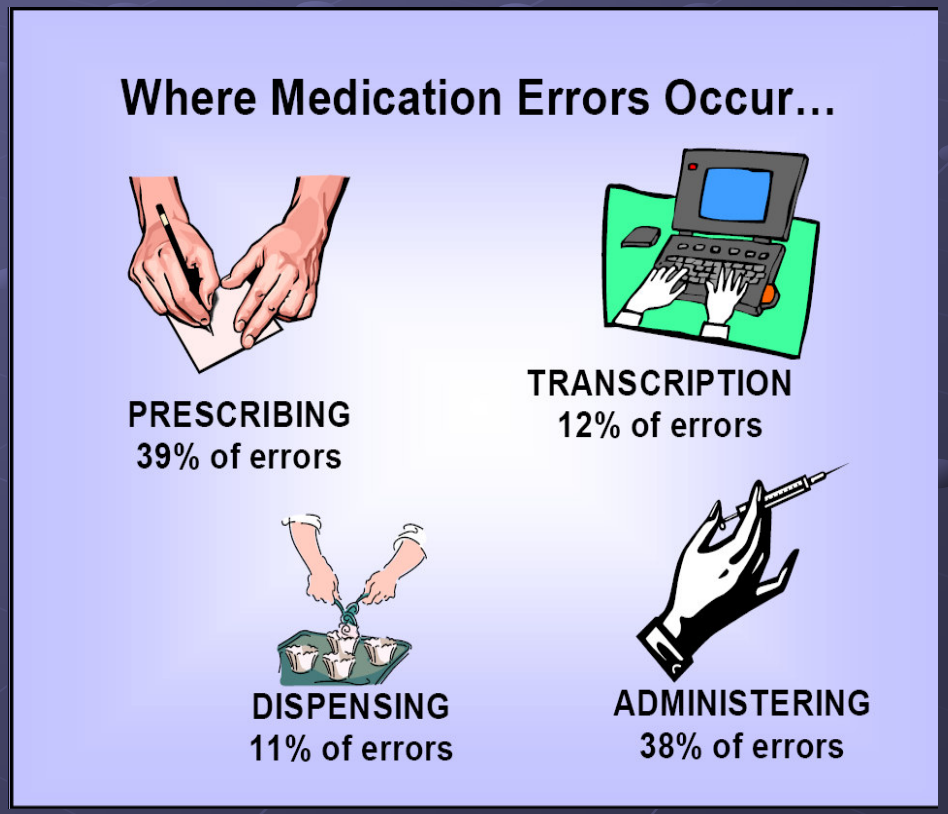
*http://www.emea.europa.eu/pdfs/human/regaffair/032898en.pdf*

Protection of public health by avoiding potential confusion with names based on objective criteria:

- Safety concerns
- INN/INN stem concerns
- Other public health concerns
- Product specific concerns

Different objective from Trade mark ™ registration process :

- Obtain legal protection for registered sign (name, logo, …)
- Distinguish goods/services from one trader to another
- Legally enforceable



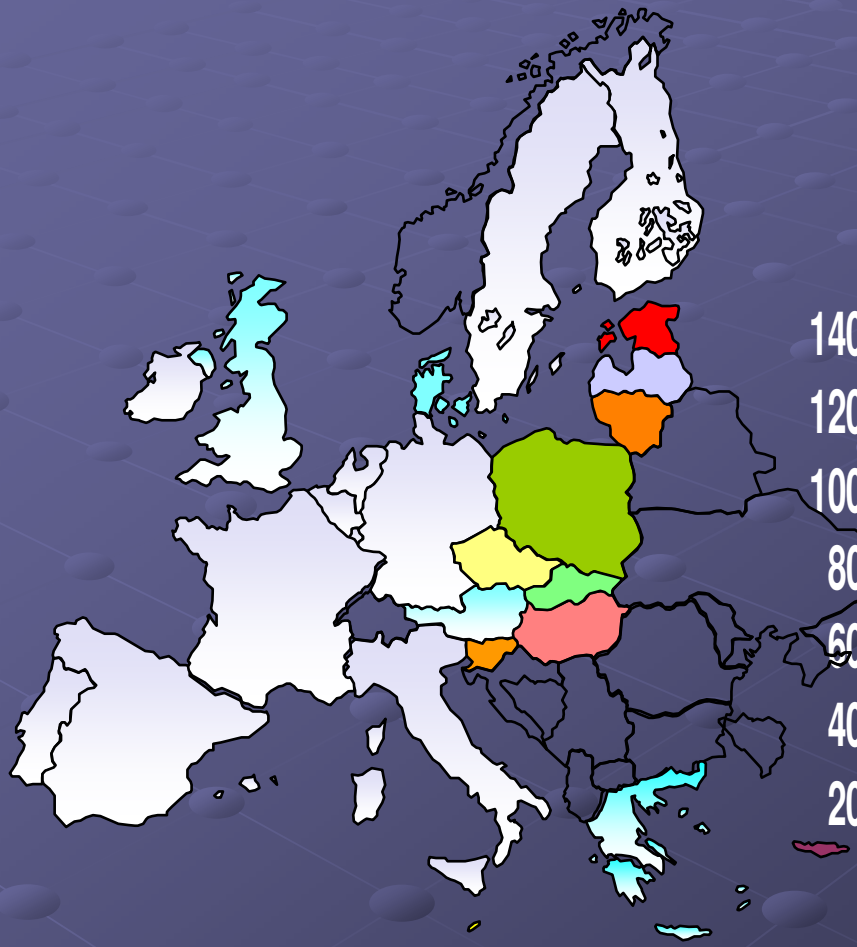
# Potential confusion in Print, Speech and/or handwriting

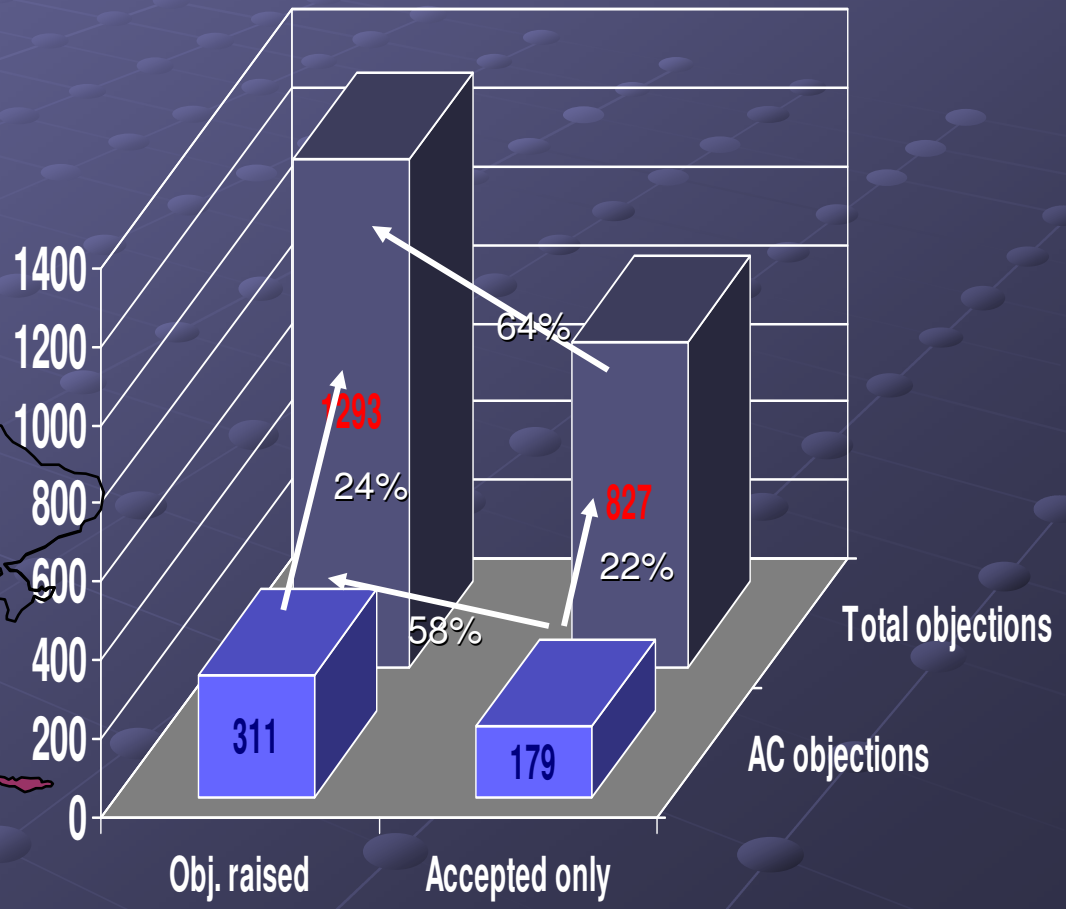
| Agenda Item | II.1.49 | | | |
|---|---|---|---|---|
| IN | **Proposed invented name** | **Luivac** | **Litak** | **ZIAC** |
| INNs/Stem | | Lysatum bacteriale mixtum | Cladribine | Bisoprolol + HCTZ |
| ATC group | | L03AX | L01BB04 | |
| MAH | | | | |
| Indication | | Treatment of recurrent respiratory infections | hairy cell leukemia | indicated in the management of hypertension |
| Strength/Ph.Form | | 3 mg/tablets | 2 mg/ml/ solution for injection | Tablets |
| RoA | | Oral use | i.v. | Oral use |
| Legal Status | Subject to medical prescription | prescription | prescription | Subject to medical prescription |
| Orphan use | NA | | | |
| Appl. Status | | Authorised:<br>CZ (year)<br>LV (date/year) | authorised:<br>Centrally<br>(year) | BE: Radiated<br>(year) |
| Multiple application | NA | | | |
| Obj. Source/ Criterion Details | | CZ: 2.1.1 - Confusion with IN<br>LV: 2.1.1 - Confusion with IN | AT: Confusio<br>with IN<br>P+S+H | on in<br>dwriting |
| NRG Discussion | | Not endorsed (different setting) | N | Endorsed |
| Conclusion | The objections were endorsed as the risk of confusion<br>deemed likely.<br>The proposed invented name is **not acceptable**. | | g with ZIAC was | |

84% NRG objections

# Proportion of objections by 10 'New' Member States

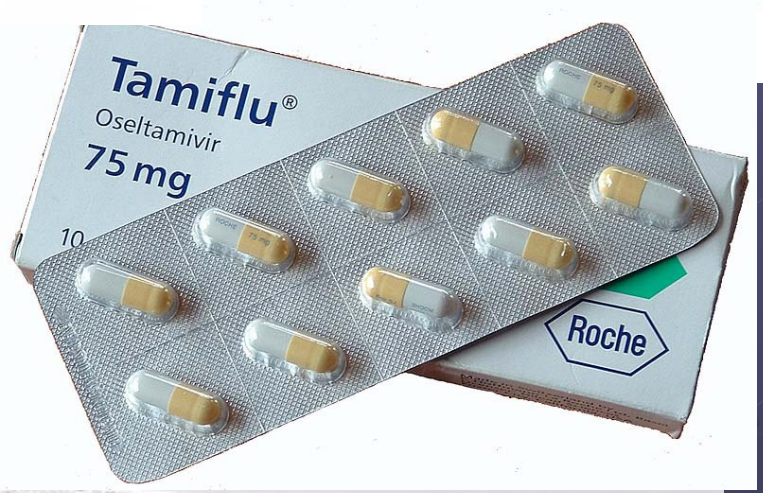
(between May '04 and Sep '06)





# Rx CAPs with ‘a connotation’

Osigraft

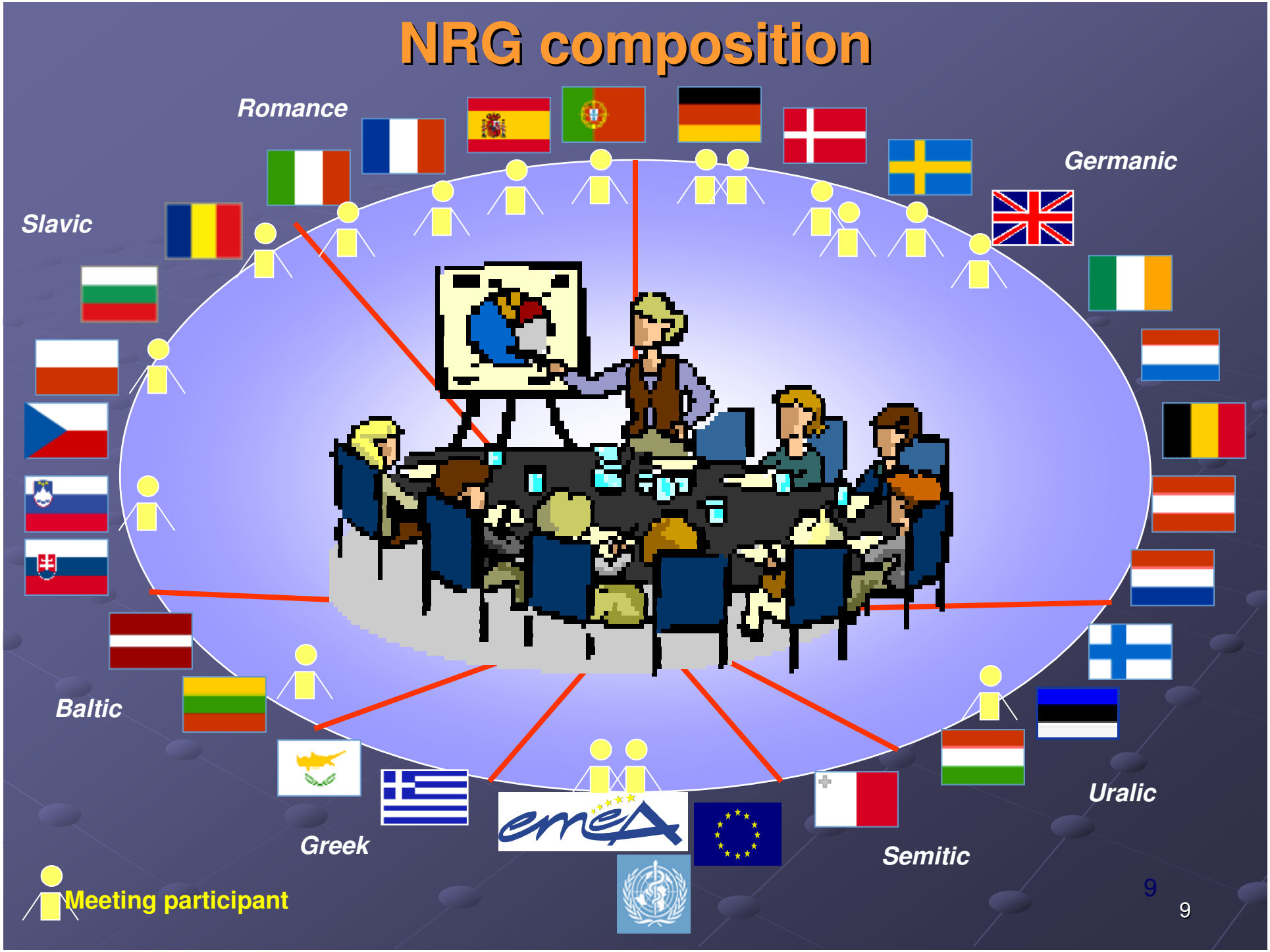



SONOVue®
Sulphur Hexafluoride

# *vs* Misleading connotation therapeutic/pharmaceutical/composition




# NRG composition





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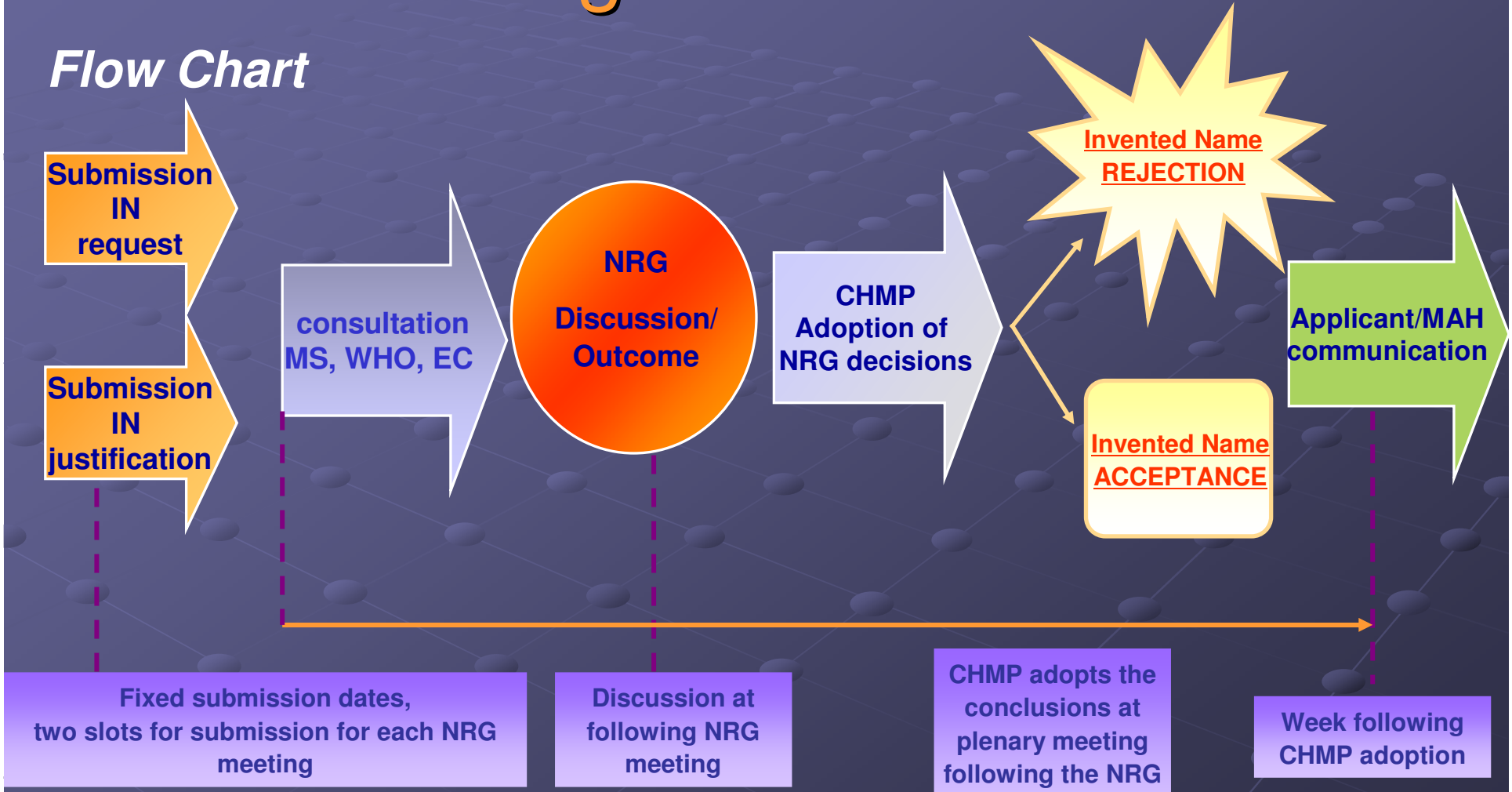
# NRG Procedure
# Checking invented names

***Flow Chart***



# NRG - EFPIA Working Group on Invented names

- Rationale
  - Facilitate dialogue on naming of medicines in the Centralised procedure
  - Facilitate discussion on specific issues of mutual importance to EFPIA and EMEA
  - 2-3 x/year

Including:

- Qualifiers glossary (incl. paediatric)
- Naming convention pre-pandemic vaccines
- …

# *FINAL Guideline on acceptability of names*

## *(CPMP/328/98 rev 5)*

- Main Changes -

- Single name requirement + exception relating to trade marks only

- Removal of 'a priori' restrictions not based on public health arguments
  - Use of qualifiers/abbreviations
  - Naming of Fixed combinations

- Extension of the scope of the Centralised procedure

  Product specific concerns:
  - Non-prescription medicinal products
  - Generic/hybrid/similar biological medicinal products

# Rx CAPs with ‘qualifiers’




# Removal ‘a priori’ restriction

## Qualifiers and abbreviations

**Section 2.3.1**

- The use of **qualifiers/abbreviations** by letters/numbers should in principle be acceptable.

NRG takes into account:

- If qualifier provides further information on characteristics of product or provides differentiation, helpful to HCP/patient to prescribe/select the MP
- Balance risks to public health in case of mix-up due to qualifier versus risk resulting from longer complex names

- Single letters or numbers not recommended – potential confusion with strength and posology

# Rx CAPs Fixed combinations with reference to ‘existing’ brand


KARVEA
KARVEZIDE





# Removal ‘a priori’ restriction

## Fixed combinations

**Section 2.3.4**

- The name should be sufficiently different from individual active or other fixed combinations

- Insertion of whole name of individual active(s) not recommended

NRG takes into account: (by analogy with “qualifiers”!)

- If name provides further information on composition or provides differentiation, helpful to HCP/patient to prescribe/select the MP
- Balance risks to public health in case of mix-up due to “qualification” versus risk resulting from longer complex names

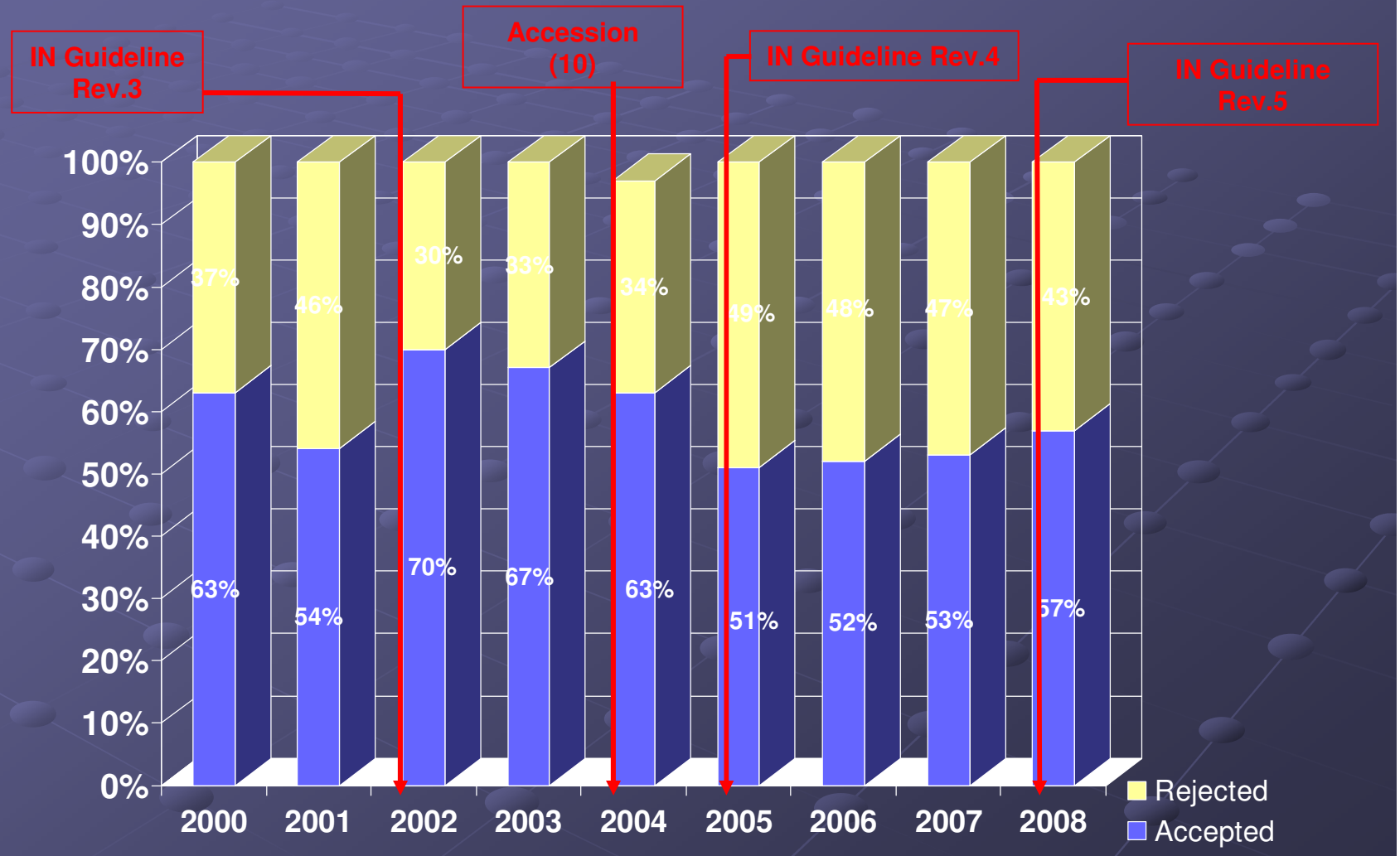
# Main challenges

- Qualifiers/Abbreviations:
  - *Limitation of what can be conveyed*
  - *Not understandable across EU*
  - Misleading therapeutic and/or pharmaceutical connotation?
  - *Potentially confusing*

- Fixed combination - Inclusion of part of the (invented) or Active substance name
  - *Insufficient difference compared to Invented name of individual active(s)*
  - *Derived from common name of individual active(s)*
  - *More common in certain therapeutic areas (e.g. insulins, cardiovascular)*
  - → *Selection in computer listings? Omission by HCP? Harm analysis?*

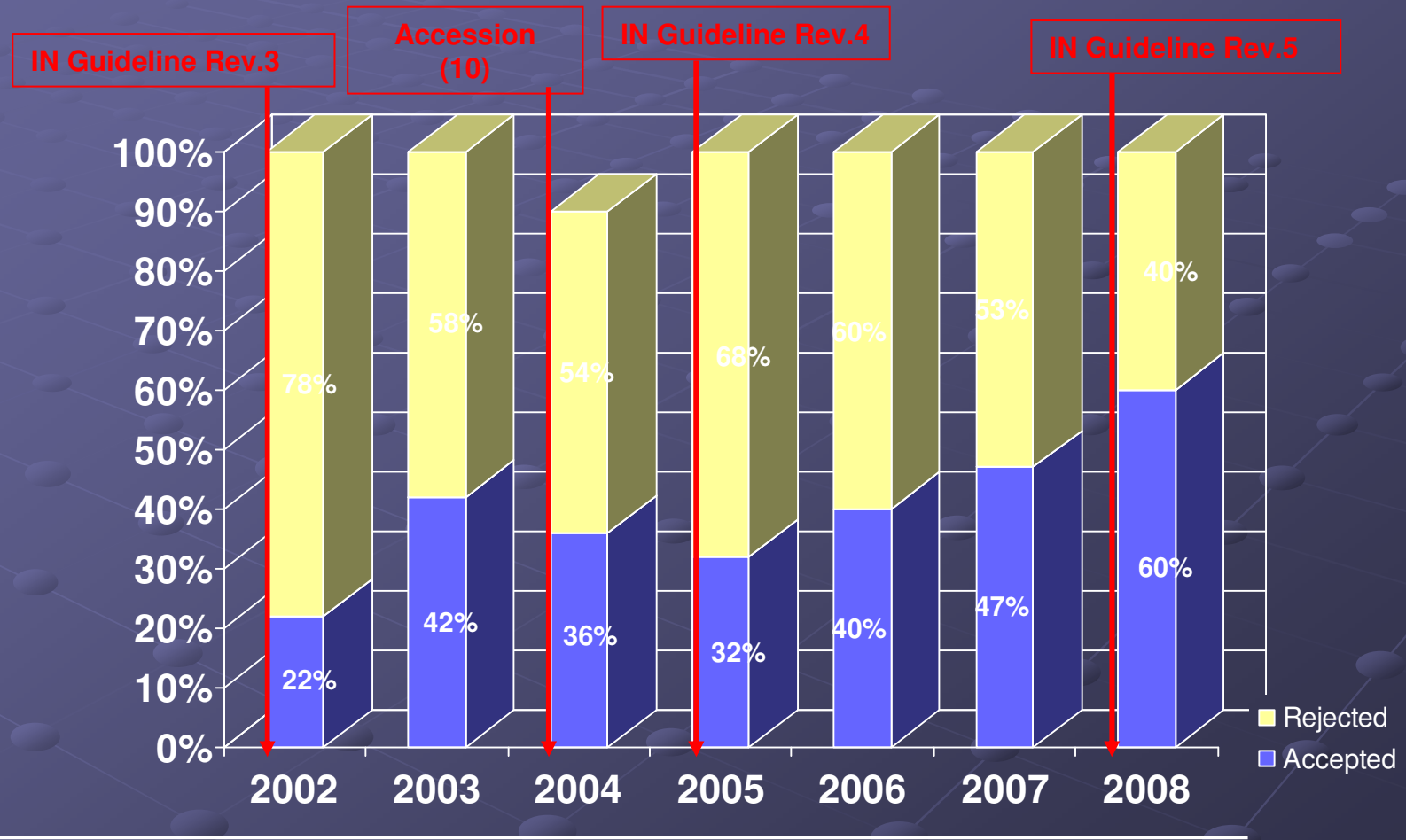
→ If "risk to public health" identified justification needed

# Overall Invented Name Review Outcome (per year)




| Total Nr INs reviewed: | 177 | 132 | 104 | 109 | 146 | 204 | 315 | 311 | 455 |
|---|---|---|---|---|---|---|---|---|---|

# FOLLOW-UP REQUESTS:
## Acceptability rate (%) after justification received from companies (per year)




| Total Nr justifications: | 9 | 12 | 23 | 24 | 43 | 55 | 30 |
|---|---|---|---|---|---|---|---|

# NRG Objections – Statistics 2008

| | 2008 |
|---|---|
| Total objections | 534 |
| CRITERION SAFETY CONCERNS | |
| Similarity with other invented names | 83.52% |
| Conveys misleading therapeutic/pharmaceutical connotations | 1.50% |
| Misleading with respect to composition | 0. 75% |
| CRITERION INN CONCERNS | |
| Similarity with INN | 2.62% |
| Inclusion of INN stem | 2.81% |
| CRITERION OTHER PUBLIC HEALTH CONCERNS | |
| Unacceptable qualifiers | 5.05% |
| Conveys a promotional message | 3.56% |
| Appears offensive or has a bad connotation | 0 |
| Similarity between name of individual active substance and fixed combinations and/or between fixed combinations | 0.19% |
| Similarity between name of prodrug and relative active substance | 0 |

Note: Several objections possible for a single proposed invented name

# NRG Objections – Statistics 2002 - 2006

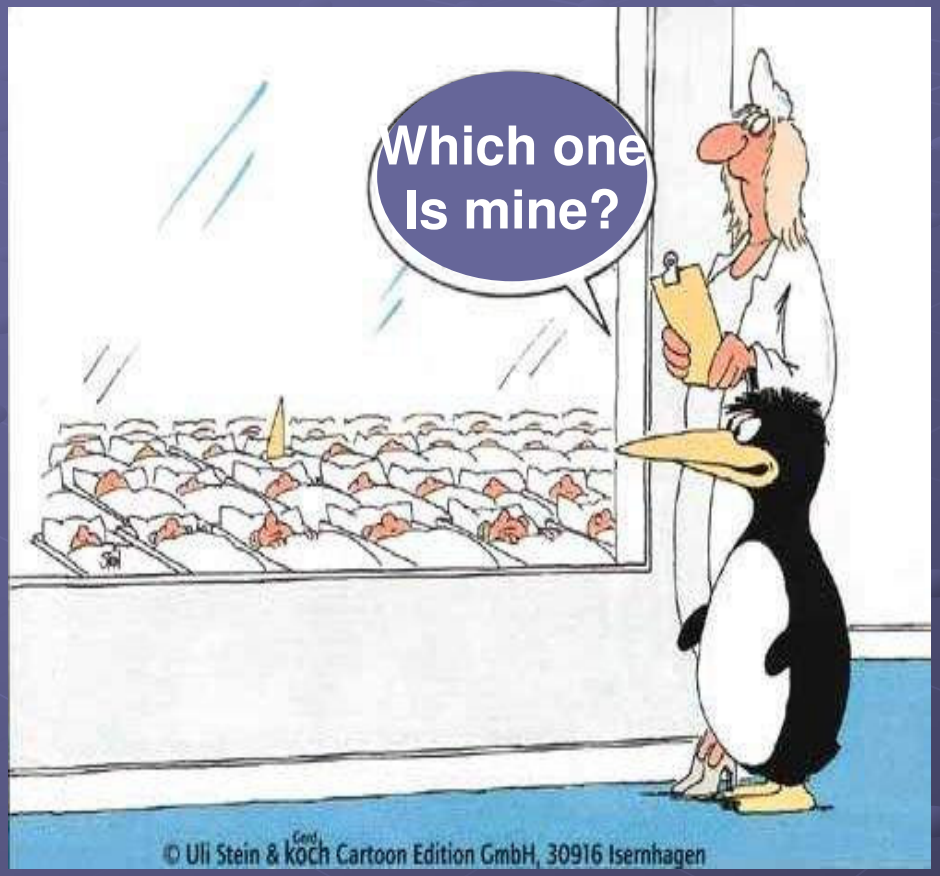
| | Until 31.01.02 | 01.02.02 to 30.04.05 | 01.05.05 to 31.07.06 |
|---|---|---|---|
| Similarity with existing invented name | 63.04% | 45.35% | 66.87% |
| More than one word; use of letters/ numbers, abbr./suffix with no established meaning | 23.55% | 24.31% | 23.50% |
| Similarity with INN/ includes INN stems | 8.70% | 13.05% | 2.31% |
| Conveys promotional/ misleading message re. use of product | 4.71% | 17.29% | 5.78% |
| Prodrug: IN should be different from IN of original AS | N/A | N/A | 1.54% |
| Total objections | 276 | 613 | 519 |

Note: Several objections possible for a single proposed invented name

# Future development and challenges

- Continue to provide effective and timely outcome of CHMP/NRG decisions to MA Applicants/MAH
- Develop further IT Tools with MSs to facilitate and exchange review
- Transparency of decisions taken – respecting confidentiality
- Medication errors - Pro-active system to be elaborated with all Stake Holders
- Develop/increase collaboration with Regulatory Authorities (e.g. FDA) and Interested parties

# Thank you very much!!!

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