Joint NRG/Interested Parties meeting on Invented names

Invented Name Review Group 2005-2006

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Chairperson NRG

Regulatory Affairs and Organisational support

11 September 2006

Agenda Topics

- Introduction
- NRG Composition/checking procedure
- Criteria addressing safety concerns
- Issues of qualifiers and bad connotation
- Fixed combinations, extensions and pro-drug
- INN/INN stem health concerns
- Product specific concerns
- A.O.B

1 – Introduction and scope

Reasons for Revision of IN guideline

- Update in line with new Community legislation
  - Single invented name requirement in Centralised procedure and definitions of name of a medicinal product and common name
  - Clarify specific aspects related to the to ‘non-prescription’ and ‘generic/hybrid/similar biological’ medicinal products. *[see disclaimer]*
- Update taking into account practice and experience gathered within the NRG since revision 4
  - Complexity within enlarged EU
- Increased transparency measures

IN Guideline
Update legal basis

Article 6 of Regulation (EC) No 726/2004,

- *"each application for the authorisation of a medicinal product (…), otherwise than in exceptional cases relating to the application of the law on trade marks, shall include the use of a single name for the medicinal product."*

Article 1(20) of Directive 2001/83/EC, as amended:

- 'the name of the medicinal product *may be either an invented name not liable to confusion with the common name, or a common name or scientific name accompanied by a trade mark or the name of the marketing authorisation holder".*

IN Guideline
- Single name rule -

CURRENT

Derogation by EC in exceptional cases where

- the proposed trade mark has been cancelled, opposed or objected to under invented name law in a Member State
- Sufficient evidence is given by MAH
- Not introduce partitioning of the EU market

IN Guideline - Single name rule -

EC INITIATIVE

- acknowledge impact of enlargement in terms of finding acceptable names across EU
- reason to re-assess application of derogation in a way that increases the options available
- invited EMEA to reflect on workable solution by review of various parameters incl.
    - Number of member states objecting on trade mark grounds
    - Resulting number of names for a single product
    - Degree of similarity/difference between the names
    - Standard of proof of objections on trademark grounds

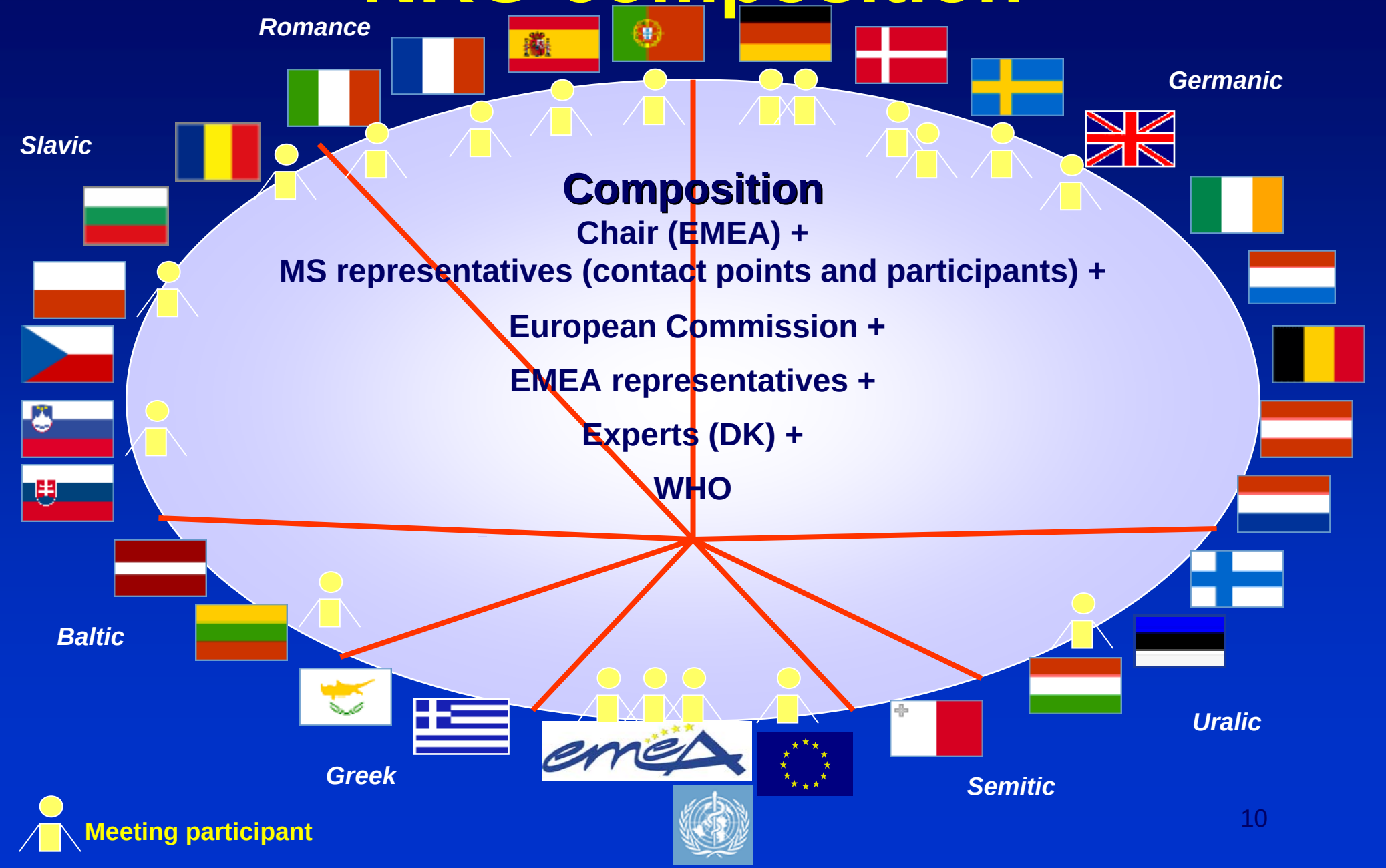
Invented Name Guideline - Revision 4

Disclaimer:

*EMEA will endeavour to update and make publicly available any **new guidance or criteria for review of invented names** in a timely manner by means of updating regularly this guideline or, if necessary separate or standalone EMEA public statements. This will be the case for instance for **invented names for "non-prescription"** and **"generics"** medicinal products for which further detailed guidance should be developed ……..*

2 – NRG Composition and Procedure for checking proposed invented names

NRG composition



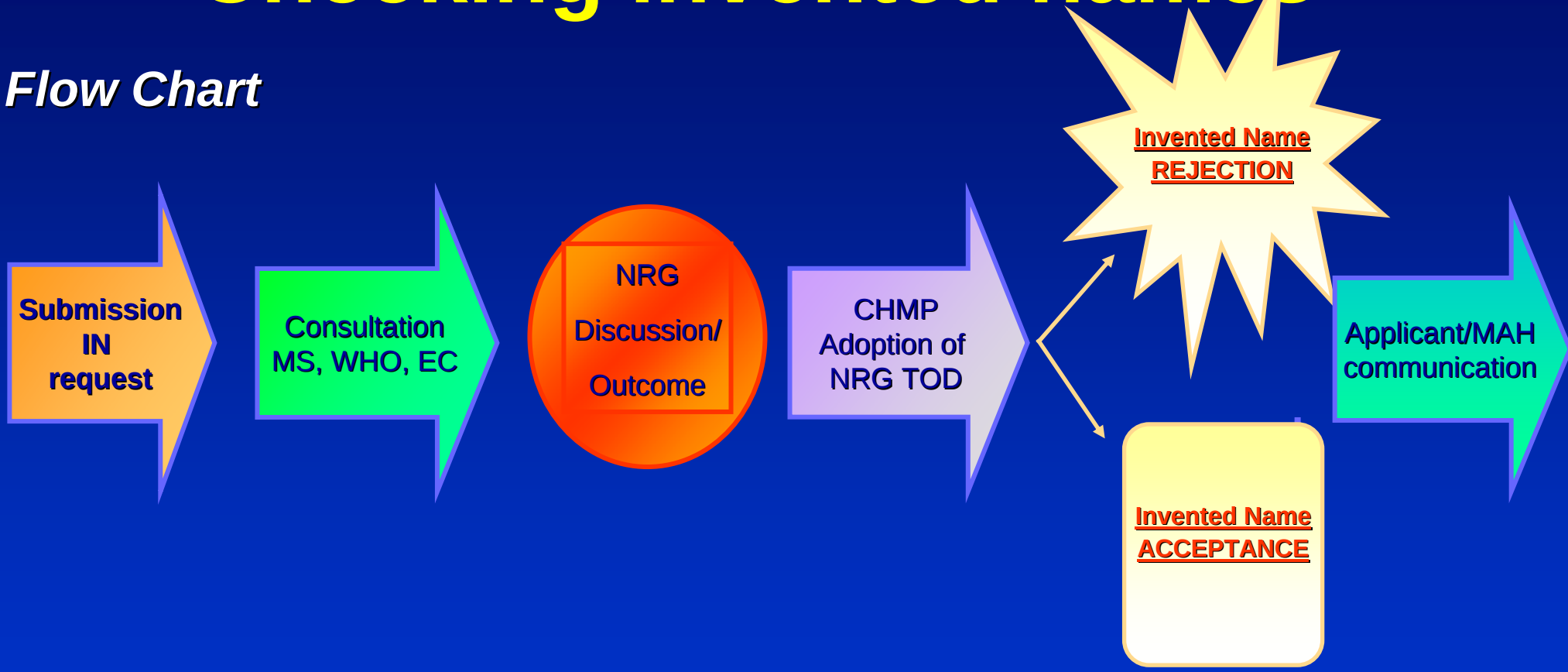
EMEA website -Transparency

Info under CHMP – Other associated groups

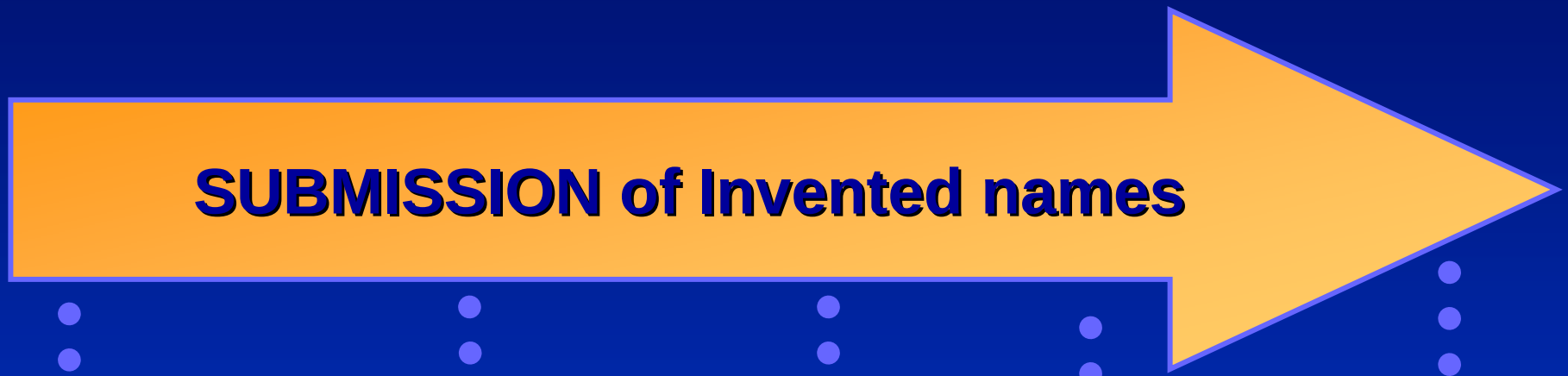
- Role NEW
- Mandate, rules of procedure, work programme *(not currently available)*
- Composition
- Members (Attendees and Contact points) NEW

NRG Procedure
Checking invented names

Flow Chart



NRG Procedure
Checking invented names



Preferably 4 - 6 months prior MAA (max 12 months before)

Invented name request form → NRG@emea.eu.int

Intended multiple applications *if applicable*

Up to 4 invented names NEW

Submission dates published (no August NRG meeting)

NRG Procedure
Checking invented names

CONSULTATION
with Member States, WHO, EC

Proposed invented name and background doc sent to NRG contact points (MS, EC and WHO)

NRG contact points to provide objections/comments on grounds of safety concerns or other within 30 days

Checking against authorised, applied for, suspended and revoked/withdrawn medicinal products according to relevant national legislation

NRG Procedure
Checking invented names

Monday CHMP week

Review of objections received based on IN guideline

Endorsement / rejection of objections

Revise Invented Name Guideline

Develop other recommendations

NRG Procedure
Checking invented names

Thursday CHMP

Week after CHMP

Present NRG Decisions to CHMP for adoption

NRG Chair informs outcome acceptability of invented name per fax

NRG Procedure
Checking invented names

Applicant / MAH Options

NRG

Invented Name REJECTION

Submission of new Invented Names

SAME PROCESS AS BEFORE

Justification for retaining proposed Invented Names

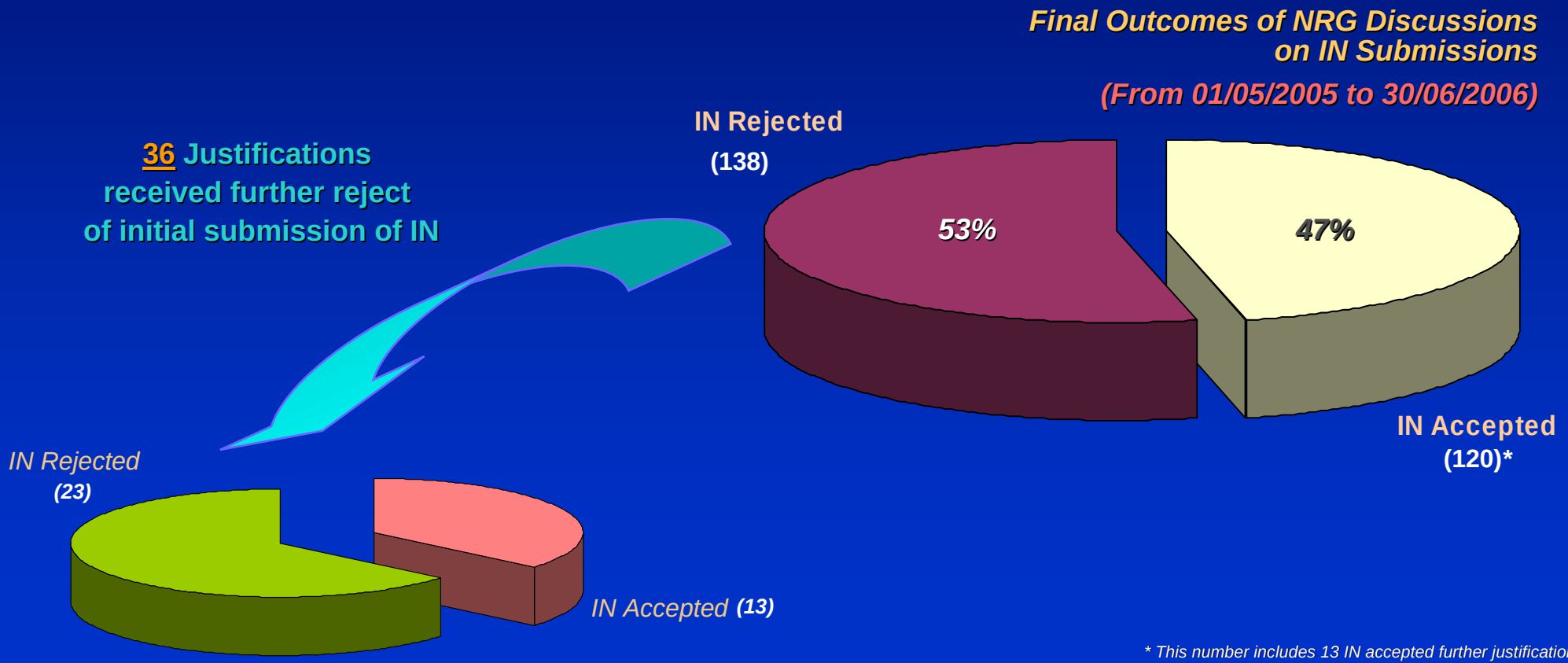
SAME PROCESS AS BEFORE

Exceptionally, MAA presents matter to CHMP during evaluation

Statistics since IN Guideline Rev.4

CHMP Monthly report NEW

Statistical information on the outcome of the NRG review on invented names

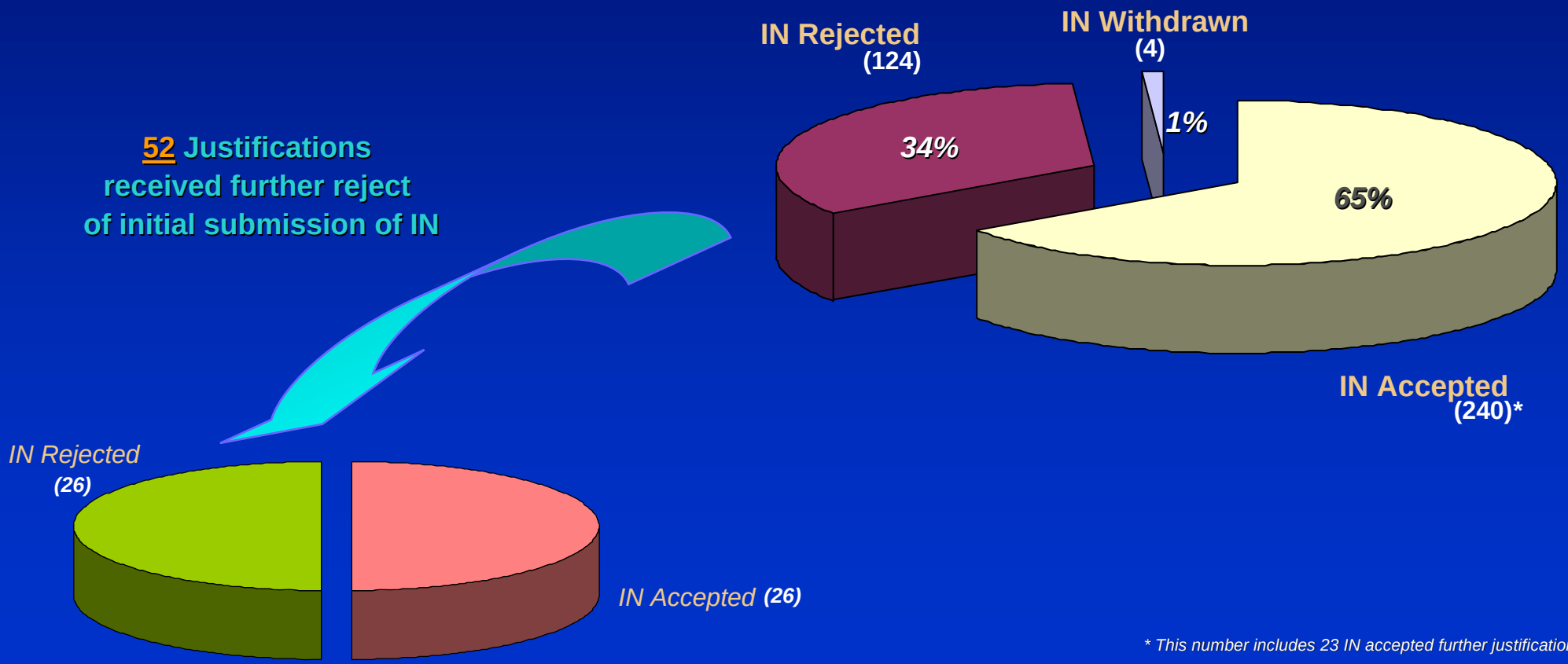


* This number includes 13 IN accepted further justification

Statistics between IN Guideline Rev.3 and 4

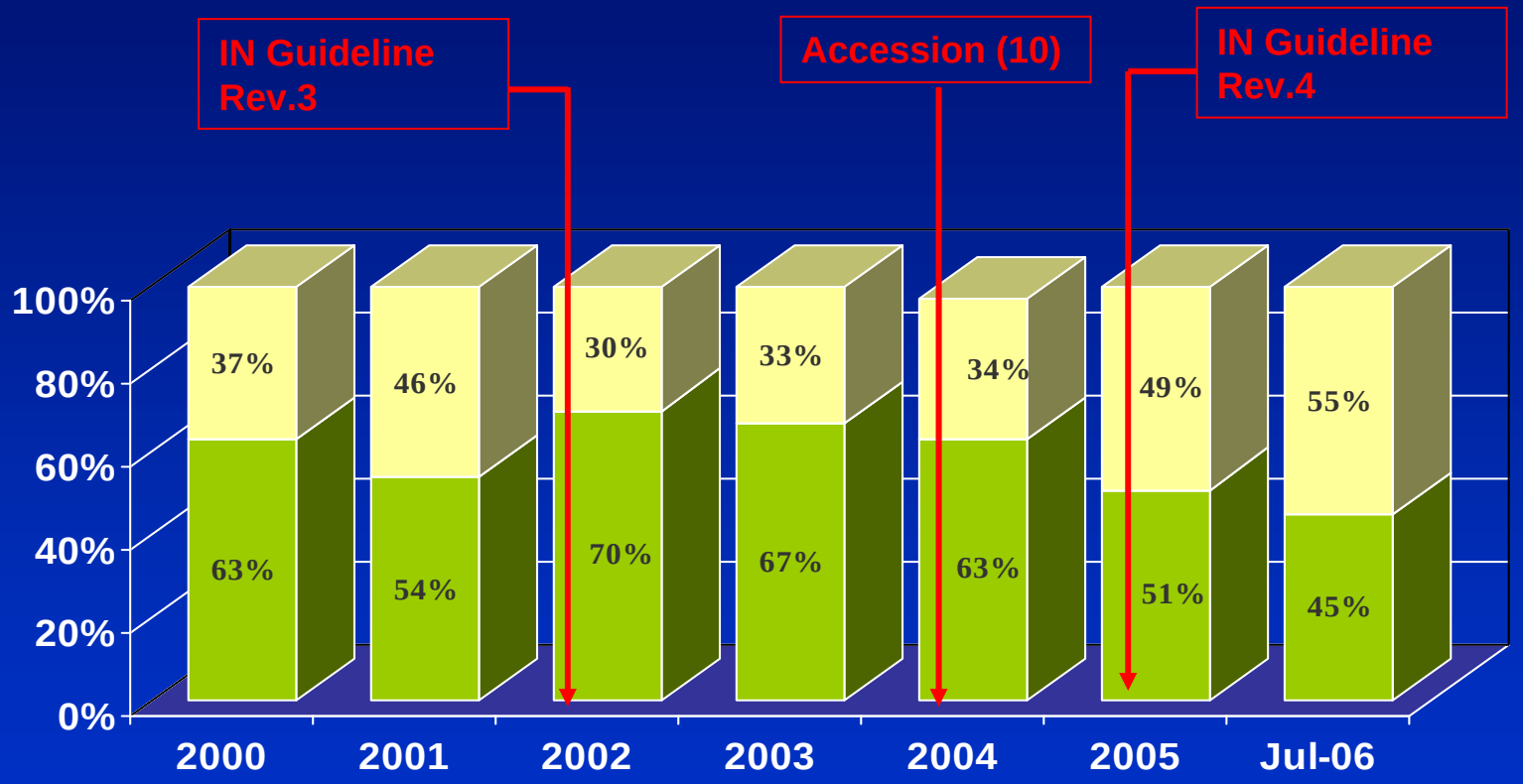
Final Outcomes of NRG Discussions on IN Submissions

(From 01/07/2002 to 30/04/2005)



** This number includes 23 IN accepted further justification*

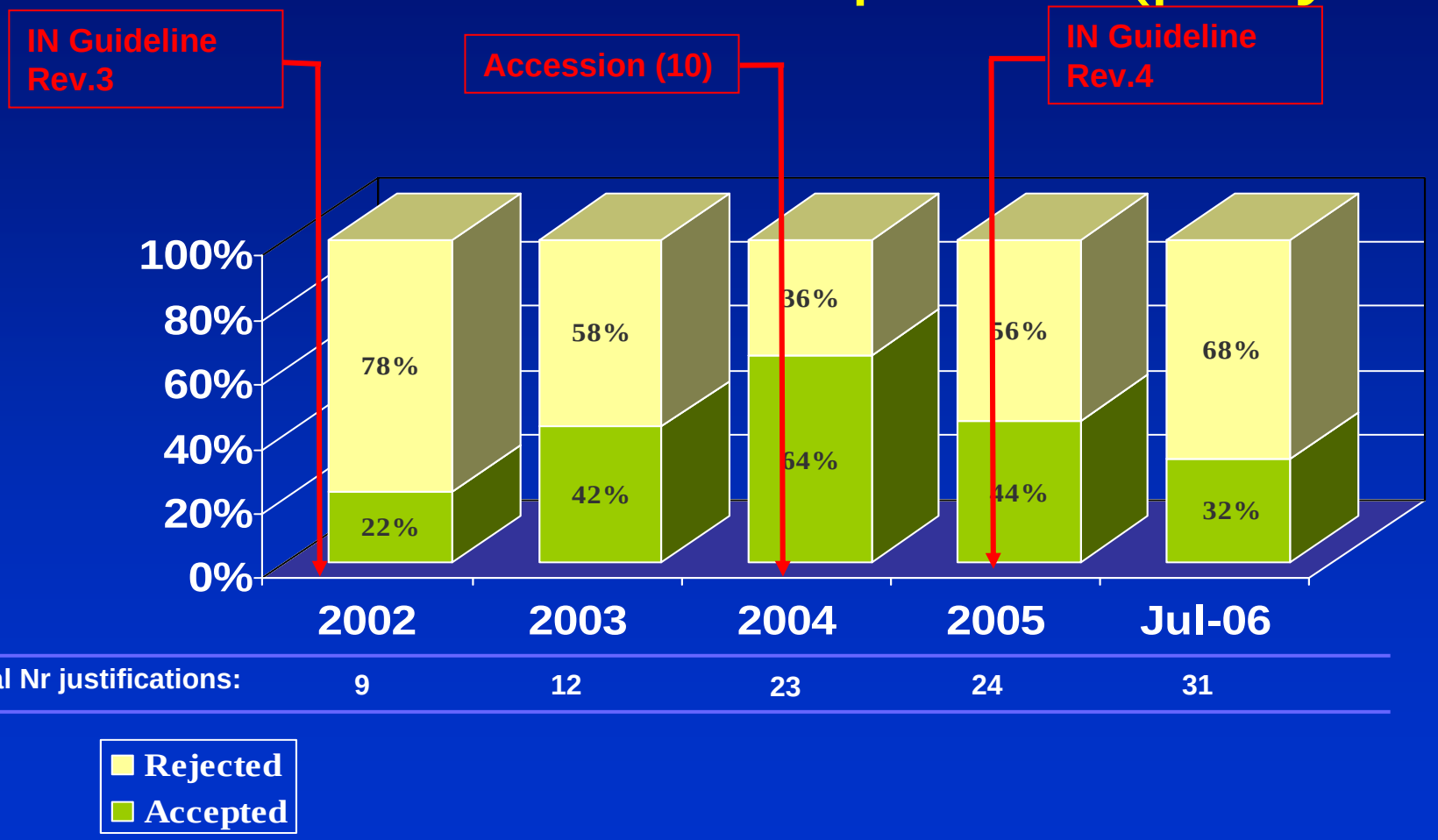
Overall Invented Name Review Outcome (per year)



Total Nr INs reviewed:	177	132	104	109	146	204	160

Rejected
Accepted

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



NRG Procedure
Checking invented names

Rejection by NRG/CHMP

- MAA can be submitted under any proposed name
- If IN not accepted by NRG within 1 month prior to opinion, CHMP will adopt it under:

  "common/scientific name + MAH"
- MAH may submit variation after Commission Decision to change (invented) name

Post-authorisation issues

- Change in (invented) name through a Type IB nr 2
- Including NRG letter of acceptance

EMEA Website - Transparency

CHMP Monthly report NEW

- Statistical information on the outcome of the NRG review on invented names in Annex 7

Annual report

- Statistical and qualitative information on the outcome of the NRG review of invented names

Criteria for review acceptability of invented names

- Safety concerns
- Other public health concerns
- International non-proprietary names (INN and INN stems)
- Product specific criteria section

3 – Criteria addressing safety concerns in proposed invented names

IN Guideline criteria
- Safety concerns -

- The Invented Name **should not**:
  - Convey misleading therapeutic or pharmaceutical connotations
  - Be misleading with respect to product composition
  - Liable to cause confusion with the invented name of an existing medicinal product in *print, speech or handwriting*

IN Guideline criteria

Section 2.3.2 (current)

The invented name should not :

- convey any promotional message with respect to the use of the medicinal product

Need for differentiation between prescription and non-prescription medicines based on legal framework?

IN Guideline criteria
- Safety concerns -

- Aspects considered during the review
  - Indication, pharmaceutical form, route of administration, strength (NEW)
  - Legal status/ classification for supply
  - Orphan designation, veterinary use
  - (Potential) new pharmaceutical form, route of administration

4 – Issue of qualifiers and bad connotation in proposed invented names

IN Guideline criteria
- Other public health concerns -

Section 2.3.1

- The invented name should preferably consist of only one word. The use of short qualifications/ abbreviations (Arabic and Roman) should in principle be **acceptable.** NEW

  Appropriate justification should be provided.

For non-prescription medicines certain aspects of the criteria described may not be applicable

Qualify what?

Examples:

- **Organs:** Gastro, Heart, Eye, Derm,...
- **Functions:** Vision, Diuretic, Flex,..
- **Conditions:** Flu, Pain, Cold, Stress,…
- **Population:** Junior, Senior, Lady, Paediatric,…
- **Properties:** Strong, Light, Express, Max, Fyto, Topical,…
- **Duration of action:** XL/L, SR, Suscaps, Depot, Retard, Forte, Compact,..

IN Guideline criteria
- Other public health concerns -

Section 2.3.3

The invented name should not :

- appear offensive or have a bad connotation in any of the EU languages
  - Case by case basis NRG may decide to inform the company without resulting in a rejection of the proposed invented name

NEW

Section 2.3.4

- The use of capitals should reflect trademark registration

5 – Fixed combinations, extension applications and prodrug containing medicinal products

IN Guideline criteria
- Other public health concerns -

Section 2.3.5

- Fixed combinations: Invented name should be **sufficiently** different from that of the individual active substances

For non-prescription medicines certain aspects of the criteria described may not apply

IN Guideline criteria
- Other public health concerns -

Since 01.01.05 the NRG reviewed:

- 42 Invented names for Fixed Combinations (FC)
- 15 accepted /27 rejected
- 10 Objections based on closeness between Invented Name of individual Active substance (AS) or with that of other FC containing the same AS

IN Guideline criteria
- Other public health concerns -

Section 2.3.6

- Pro-drug: IN should be sufficiently different from IN of MP containing related active substance.

IN Guideline criteria
- Other public health concerns -

Section 2.3.7

Extensions (Annex II to CR 1085/2003):

- Same IN as existing MP, apart from the justified qualifications/abbreviations mentioned under Section 2.3.1
- In case the applicant wants to file an extension as a full and standalone application (if applicable according to the legislation), a separate MAA must be submitted under a different invented name.

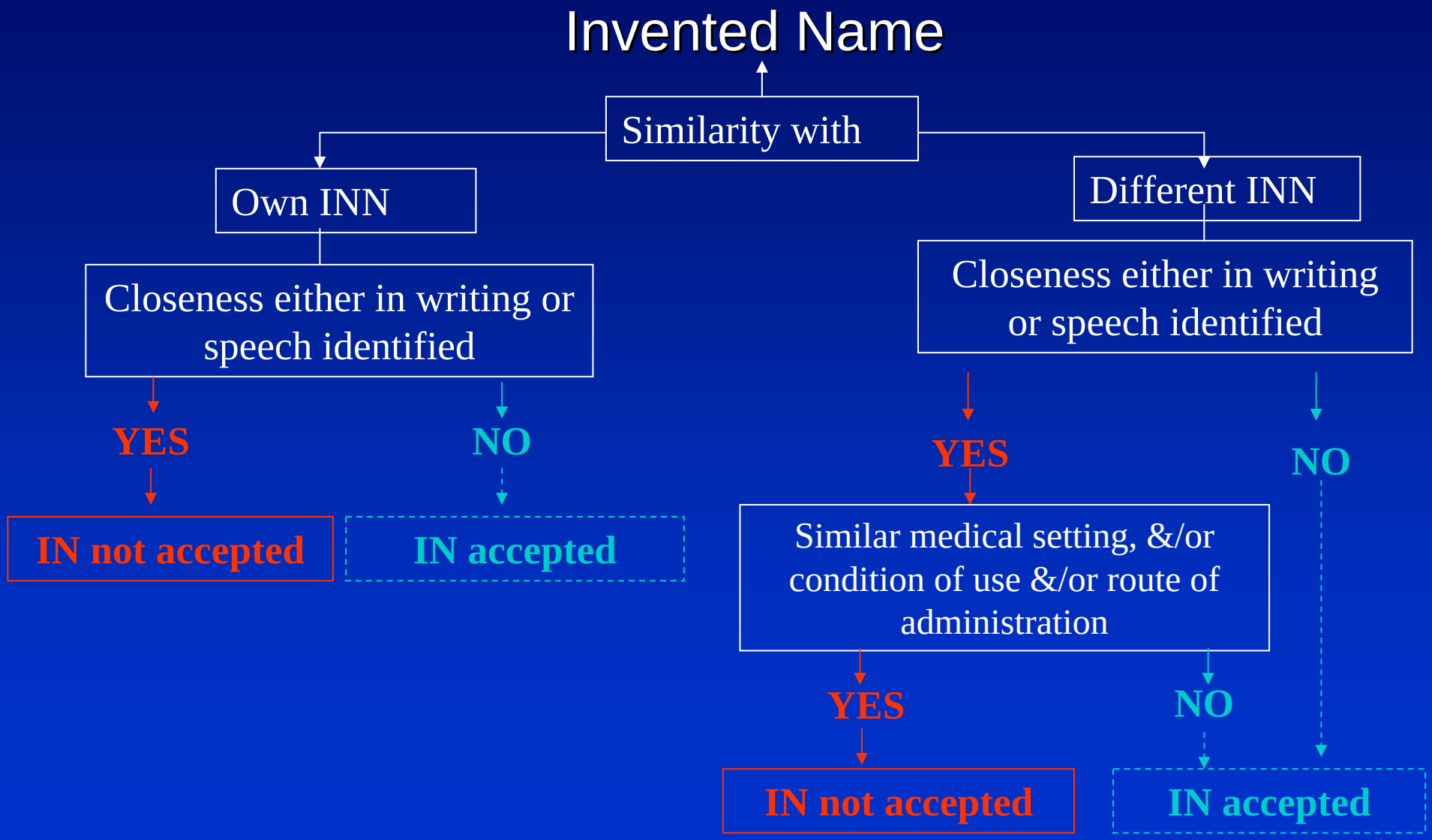
Grounds for Objections
- Statistics -

	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

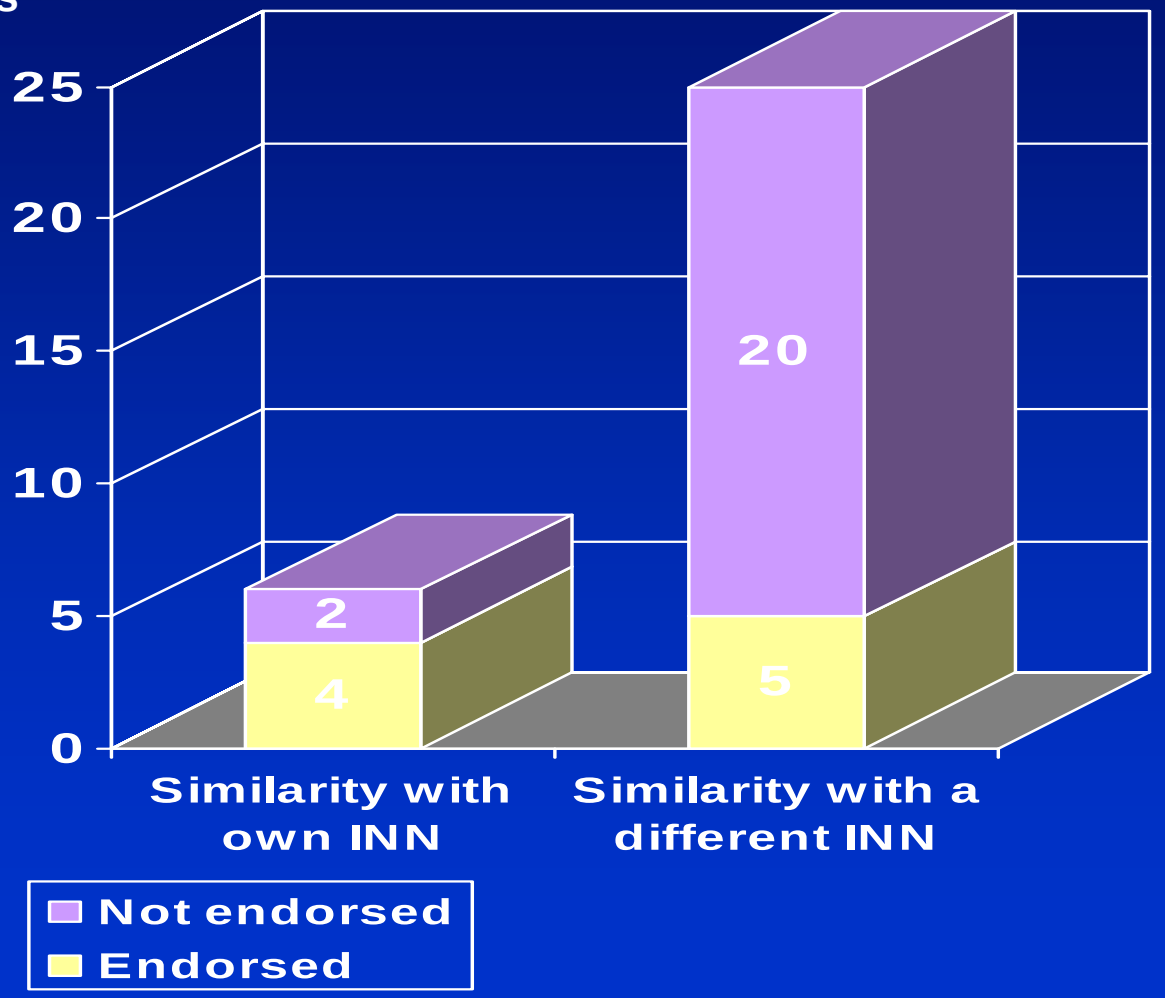
6 – INN/INN stem health concerns in proposed invented names

Decision tree - INN similarity

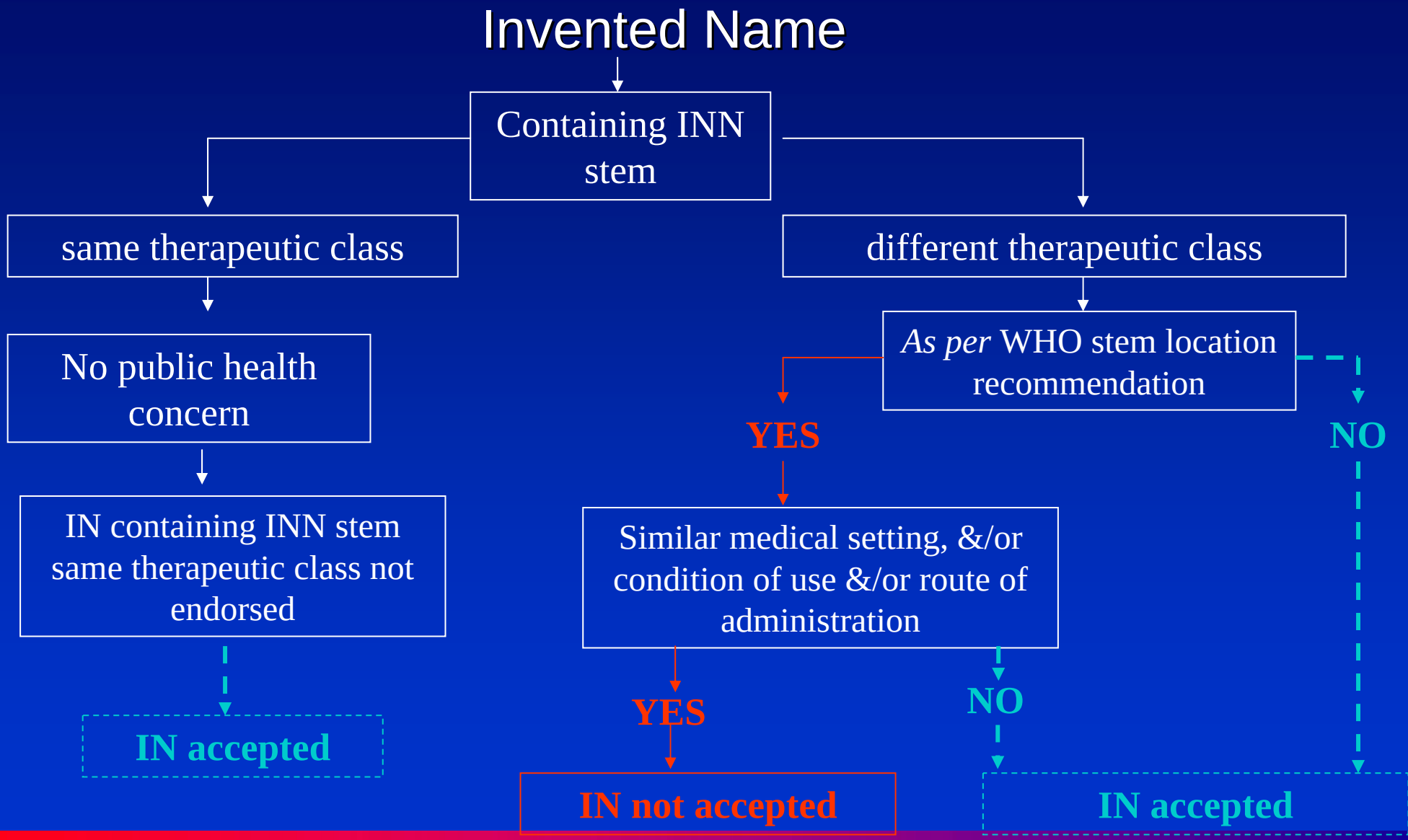


INN related objections Since July 2004

Similarity with existing INNs

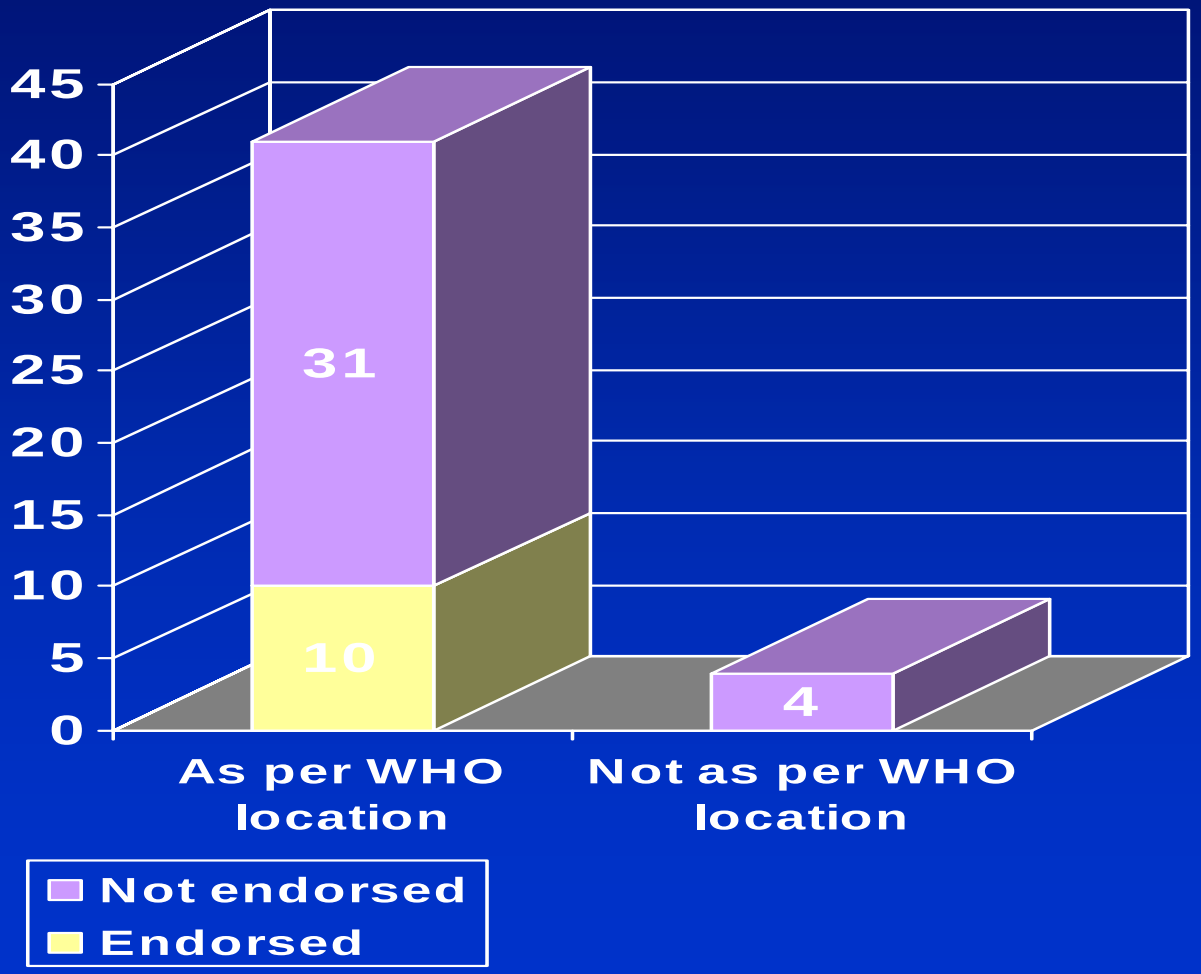


Decision tree - INN stem inclusion



INN stem related objections Since July 2004

Inclusion of INN stems



IN Guideline
INN/INN stem similarity

- Applicant/MAH to undertake
  - Review of INN/INN stem similarities prior to submitting their proposed invented names
  - Address any issues arising from the above in the application form or provide a justification for deviation

IN Guideline
INN/INN stem similarity

Transparency

NEW

- Proposal to include INN decision trees in IN guideline
- Links to INN related information on WHO website updated

7 – Product specific concerns in proposed invented names

IN Guideline criteria
- Product specific criteria -

Separate section for the following type of products:

- Vaccines
- Biological MP
- Orphan MP

NEW

AND NOW…

- Non-prescription MP
- Generic/Hybrid/ similar biological MP

IN Guideline criteria
- Product specific criteria -

Biological medicinal products:

- Manufacturing changes leading to a new version of the product replacing the old one: same invented name may be maintained
- Change in characteristics of the medicinal product: a new invented name may be necessary.

➔case-by-case review

IN Guideline criteria
- Product specific criteria -

Non-prescription medicinal products:

- Due account to be made of specific legal environment associated with this category of MPs
- In view of differences in diagnosis, selection/identification of the appropriate medicinal product by the patient/pharmacist and the absence of a 'prescription-dispensing' transcription phase, **specific limitation** described **under sections 2.3.1, 2.3.2 and 2.3.5 may not apply**.
- Appropriate justification should be provided. E.g. Benefit to the selection/identification of the medicinal product by the patient and lack of inappropriate use.

IN Guideline criteria
- Product specific criteria -

Non-prescription medicinal products:

- In case of a switch from **“prescription” to “non-prescription”** status, the applicant/MAH may retain the same IN or choose a new one. In exceptional cases, depending on the therapeutic context, the acceptability of the proposed invented name may be further considered as part of the review process.

IN Guideline criteria
- Product specific criteria -

Generic/hybrid/similar biological MP:

- The same criteria apply as for any other medicinal products in respect to the invented name

IN Guideline criteria
- Product specific criteria -

Where the applicant/MAH wishes to use instead of the invented name the common name/ scientific name + trademark/ name of MAH, the following applies:

- INN recommended by WHO should be used exactly as published (including all linguistic versions). If no INN exist, the usual common name should be used;
- The use of hyphens and/or other symbols is not allowed

IN Guideline criteria
- Product specific criteria -

How to represent:

- 'Name of MAH' = official name of the MAH
  Excluding character of corporate personality (e.g Limited, SA, Sprl) and/or qualifiers?;

How to interprete:

- 'Trademark'

  Trademarked representation of the applicant/MAH?

Next Steps

- Development of single name rule exceptions
- Discussion of IN guideline with NRG, CHMP, European Commission
- Release for consultation to Interested Parties

Abbreviations

- WHO World Health Organisation
- MP Medicinal Product
- IN Invented Name
- MAA Marketing Authorisation Application
- MAH Marketing Authorisation Holder