# Joint NRG/EFPIA Workshop on Invented names

## Invented Name Review Group (NRG) 2005-2006

**Zaide FRIAS**

**Chairperson NRG**

**Regulatory Affairs and Organisational support**

**11 September 2006**

# Topics

- Introduction and scope of Workshop
- NRG Checking procedure
- Criteria addressing safety concerns
- Criteria addressing INN/INN stem concerns
- Criteria addressing other public health concerns
- Transparency
- Invented name and enlargement

# 1 – Introduction and scope

# Purpose of NRG/EFPIA Workshop

**Exchange of information to:**

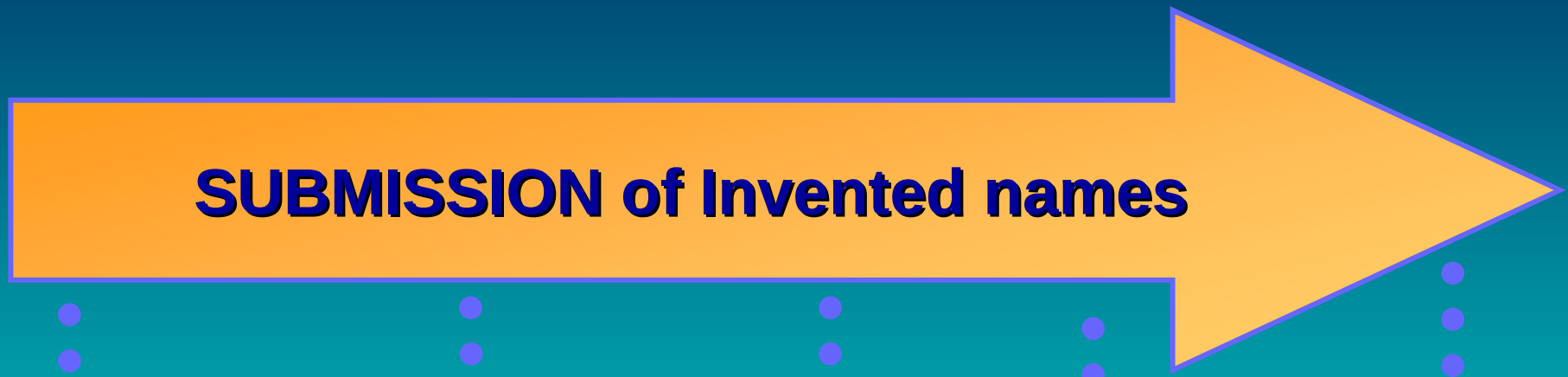
- Improve predictability of NRG outcome
- Provide recommendations to Industry to improve overall efficiency of process

# 2 – NRG procedure for checking proposed invented names

# 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)

# Recommendations

Companies to avoid:

- Submission of (three) very similar names in terms of print, speech and handwriting
- Submission of (three) invented names deviating from the same criterion (e.g. use of qualifier ‘XRS’)

These can be submitted as new invented name(s) in parallel with a justification of the originally proposed invented name

# Submission dates for proposed invented names

Deadlines for submission of Proposed Invented Names and dates of NRG discussion/CHMP adoption follow the CHMP time schedule, as follows:

| 2006 | | 2007 | | 2008 | |
|---|---|---|---|---|---|
| Submission Deadline | Discussion/Adoption | Submission Deadline | Discussion/Adoption | Submission Deadline | Discussion/Adoption |
| 18 January | 20-23 February | 17 January | 19-22 February | 16 January | 18-21 February |
| 15 February | 20-23 March | 14 February | 19-22 March | 13 February | 17-20 March |
| 15 March | 24-27 April | 14 March | 23-26 April | 12 March | 21-24 April |
| 19 April | 29 May - 1June | 16 April | 21-24 May | 16 April | 26-29 May |
| 24 May | 26-29 June | 16 May | 18-21 June | 21 May | 23-26 June |
| 21 June | 24-27 July | 13 June | 16-19 July | 18 June | 21-24 July |
| 19 July | 18-21 September | 11 July | 17-20 September | 16 July | 22-25 September |
| No invented name review procedure in August | | | | | |
| 13 September | 16-19 October | 12 September | 15-18 October | 17 September | 20-23 October |
| 11 October | 13-16 November | 10 October | 12-15 November | 15 October | 17-20 November |
| 8 November | 11-14 December | 7 November | 10-13 December | 12 November | 15-18 December |
| 6 December | 22-25 January 2007 | 5 December | 21-24 January 2008 | 10 December | January 2009 |

# REQUEST FORM – Proposed invented name(s)

**REQUEST FORM**
**Proposed Invented Name(s)**

*This form should be read in conjunction with the 'Guideline on the Acceptability of invented names for human medicinal products processed through the centralised procedure (CPMP/328/98)*

Date:

**Applicant's Details:**

| | | |
|---|---|---|
| **Applicant/ MAH Name** | : | |
| **Applicant/ MAH Address** | : | |
| **Contact Person Details (inc. Fax Number)** | : | |

**Product information:**

| | | |
|---|---|---|
| **Proposed Invented Name 1[1]** | : | |
| **Proposed Invented Name 2** | : | |
| **Proposed Invented Name 3** | : | |
| **Proposed Invented Name 4** | : | |

# REQUEST FORM – Proposed invented name(s)

| | | |
|---|---|---|
| **INN**[2] | : | |
| **Intended Indication(s)** | : | |
| **Strength(s)** | : | |
| **Pharmaceutical Form (including medical device)** | : | |
| **Route(s) of Administration** | : | |
| **Scope** | : | Mandatory ☐<br>Optional ☐<br>Orphan Drug Designation ☐<br>(Granted on: ) |
| **Legal basis for submission** *(According to Directive 2001/83/EC, as amended)* | : | Article 8 (3) |
| **Change in the Invented Name** | : | Not applicable ☐<br>Current name: |

[1] Please note that the invented name will be reviewed as written (e.g. upper case, sentence case…)
[2] If not available, please state INN applied for with WHO or scientific name

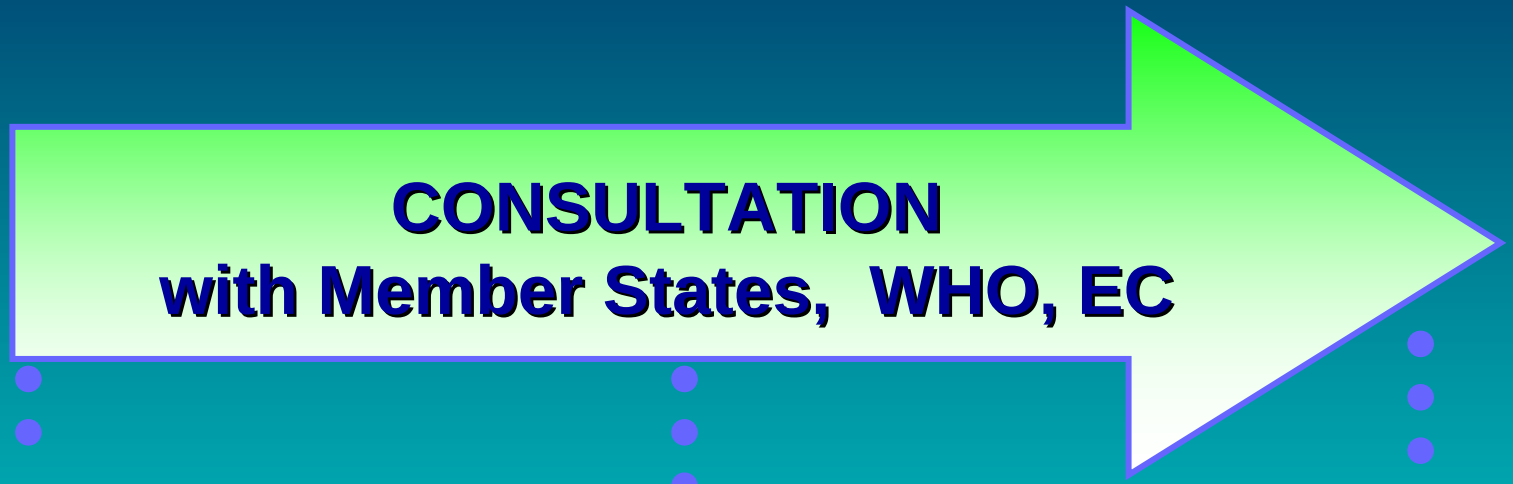
# REQUEST FORM – Proposed invented name(s)

| | | |
|---|---|---|
| **Proposed Legal Status** *(According to Directive 2001/83/EC, as amended, Title VI)* | : | Subject to Medical Prescription ☐<br>Not subject to Medical Prescription ☐<br>If Subject to Medical Prescription:<br>Product on special medical prescription ☐<br>Product on restricted medical prescription ☐ |
| **Intended Submission Date** | : | |
| **Multiple applications**[3] | : | Not applicable ☐<br>Indicate number: |
| **Generic/ hybrid/ similar biological medicinal product** | : | Not applicable ☐<br>Reference medicinal product: |
| **Invented Names previously reviewed**[4]**/ outcome date** | : | |
| **Justification for deviation from the Guideline** | : | |
| **Other relevant Information** | : | |

[3] Where proposed invented names are intended for use in the context of multiple marketing authorisation applications, the applicant shall specifically request the NRG to consider potential risks of confusing of these invented names with each other.

[4] For the same medicinal product

# NRG Procedure
# Checking invented names




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

# Consultation with Member States, WHO, EC

- Checking against authorised, applied for, suspended and revoked/withdrawn medicinal products according to relevant national legislation
  - Problems when NRG objection concerns a pending authorisation – no transparency
  - Explore possibility for harmonisation of rules for CAPs?

# 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 review statistics

| | Nov'99 – Jul'04 | Nov'99 – Jul'06 | Jan'- Jul' 06 |
|---|---|---|---|
| Average number of INs reviewed per month | 14.5 | 17.5 | 21.1 |
| Average of objections received per IN | 3.2 | 3.9 | 4.9 |
| Average INs per INN | 3.1 | 1.9 | 2.0 |

# NRG Procedure
# Checking invented names

*Thursday CHMP*

*Week after CHMP*

# NRG Procedure checking invented names

NRG Outcome fax template amended

- Same person preparing letters
- Review and signed-off by Chair

→ improved consistency!

# Outcome fax template

European Medicines Agency
Evaluation of Medicines for Human Use

**TELEFAX MESSAGE**

| | | | |
|---|---|---|---|
| **DATE:** | *<date>* | **OUR REF:** | EMEA/xxxx/2006 |
| **TO:** | *<Company's contact person 's name>* | **PHONE:** | *<Company 's phone number>* |
| | *<Company's name>* | **FAX:** | *<Company 's fax number>* |
| **FROM:** | *Zaïde Frias* | **PHONE:** | (44-20)-*<NRG Chair phone number>* |
| | NRG Chairperson | **FAX:** | (44-20)-*<NRG Secretariat fax no>* |
| **RE:** | ***<Invented name(s)>*** *(INN)*- Outcome of the *<date>* CHMP meeting. | | |
| Number of Pages (including cover sheet): → | | | |

Original of this fax has been signed by the sender and is available upon request from the signatory.

**MESSAGE**

Dear Mr*<(s)>* *<Company's contact name>*,

In response to your *letter/e-mail* dated *<date>*, I would like to inform you of the outcome of the CHMP discussion which took place during the plenary CHMP meeting held on *<date>*.

# Outcome fax template

¶

We· are· pleased· to· inform· you· that,· further· to· liaison· with· national· competent· authorities· and· subsequent·discussion·at·the·invented·Name·Review·Group·(NRG),·the·CHMP·has·no·objections·to· the·invented·name(s)·<***list·of·company's·proposed·invented·names***>·for·<*INN*>.¶

¶

The·invented·name·review·is·valid·at·the·present·point·in·time,·which·does·not·prohibit·the·possibility· of·objections·being·raised·in·the·future·prior·to·the·granting·of·the·marketing·authorisation.¶

¶

However,·the·CHMP·during·the·same·meeting·has·also·decided·that·the·following·invented·name(s)· raise·identifiable·safety·issues·and·therefore·cannot·be·accepted:¶

¶

<***Invented·Name·(INN)***>:¶

the·specific·concern·identified·is·that·this·invented·name·could·¶

- <·*be·liable·to·cause·confusion·in·print,·handwriting·or·speech·with·the·invented·name·of·an·existing· medicinal·product·*<invented·name·which·is·compared·to>*which·is··<marketed>·or·<authorised>·in· e.g.·<name·of·the·Member·State>·<and>*·¶
- <·*convey·misleading·therapeutic·or·pharmaceutical·connotations*>.¶
- <·*be·misleading·with·respect·to·the·composition·of·the·product*>.¶

*<The·INN·stem·(*<stem>*)·should·not·be·used·in·the·proposed·invented·name·('*<stem>*'·is·an·INN·stem· which·refers·to·*<indication>*)·taking·into·account·the·potential·similar·pharmaceutical·form,·route·of· administration·and/or·medical·setting.*¶

·¶

[*For·further·arguments,·please·refer·to·the·relevant·monthly·NRG·Table·of·Decision*]¶

¶

For·each·invented·name·repeat·the·following·paragraph,·were·appropriate¶

IF·THIS·FAX·IS·ILLEGIBLE·OR·INCOMPLETE,·PLEASE·CALL·THE·PHONE·NUMBER·ABOVE¶

¶

7·Westferry·Circus,·Canary·Wharf,·London,·E14·4HB,·UK¶

Tel.·(44-20)·74·18·84·00···Fax·(44-20)·75·23·70·51¶

# Outcome fax template

¶
You· may· propose· a· justification· for· retention· of· your· proposed· invented· name(s)· using· the· justification· form· published· on· the· EMEA· website (http://www.emea.eu.int/htms/human/presub/IN%20justification%20form.doc)·and·provide·arguments· countering·the·concern(s)·identified.¶
¶
Should·you·intend·to·submit·alternative·invented·names,·please·be·aware·that·you·will·need·to·inform· the·EMEA·(PTL)·and·the·NRG·Secretariat·on·the·acceptable·invented·name·of·your·choice·at·the·latest· one·month·prior·to·the·adoption·of·the·CHMP·opinion·of·the·concerned·MAA.·¶
If·no·suitable·invented·name·has·been·identified·at·that·stage,·the·opinion·will·be·adopted·according·to· the·common·name·or·scientific·name·accompanied·by·the·name·of·the·Marketing·authorisation·Holder.¶
In·accordance·with·Commission·Regulation·(EC)·No·1085/2003,·the·name·of·the·medicinal·product· may·always·be·changed·after·authorisation·through·a·Type·IB·variation.¶
¶
Yours·sincerely,·¶
¶
¶
¶
Zaïde·Frias¶
NRG·Chairperson¶
¶

# Recommendations

Contact NRG Chair:

- In case of doubt on the outcome fax; or
- When preparing a justification for maintaining a proposed invented name; or
- When exploring possible alternative solutions

# Recommendations

Prior to preparing justification:

- Where source of objection is identified in outcome fax, companies to check authorisation/marketing status of the concerned medicinal product across the EU
- Reference to availability of (global) trade-mark not sufficient to justify maintenance of IN

# NRG Procedure
# Checking invented names


*Applicant / MAH*

**Submission of new Invented Names**

**Justification for retaining proposed Invented Names**

**Exceptionally, MAA presents matter to CHMP during evaluation**

*NRG*

**SAME PROCESS AS BEFORE**

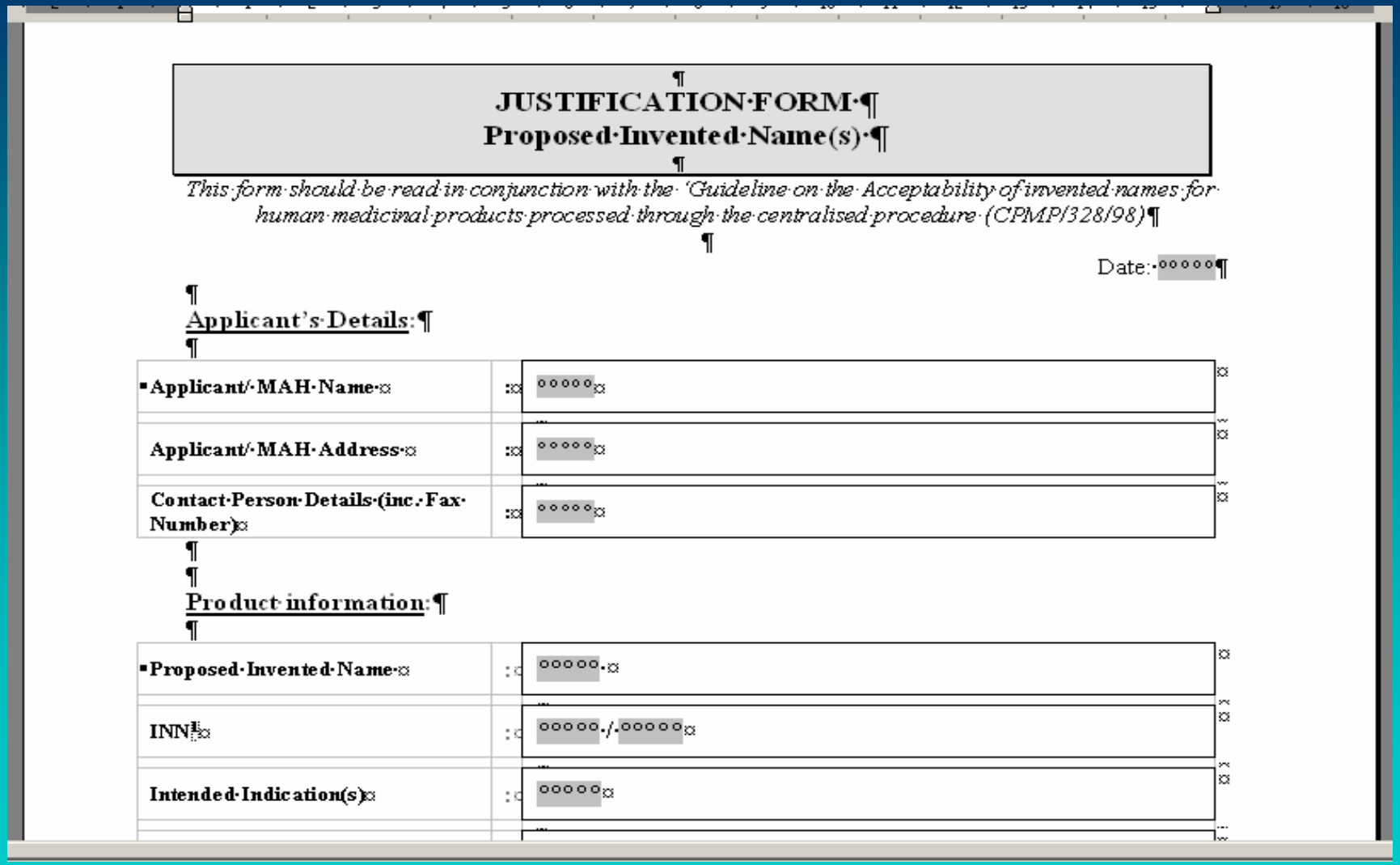
**SAME PROCESS AS BEFORE**

# Recommendation(s)

In case of rejection of proposed IN:

- Try to amend your proposed invented name to take it away from the potentially confusing names
- These can be submitted as new invented name(s) in parallel with a justification of the originally proposed invented name

# JUSTIFICATION FORM – Proposed invented name(s)



**JUSTIFICATION FORM**
**Proposed Invented Name(s)**

*This form should be read in conjunction with the 'Guideline on the Acceptability of invented names for human medicinal products processed through the centralised procedure (CPMP/328/98)*

Date: ooooo

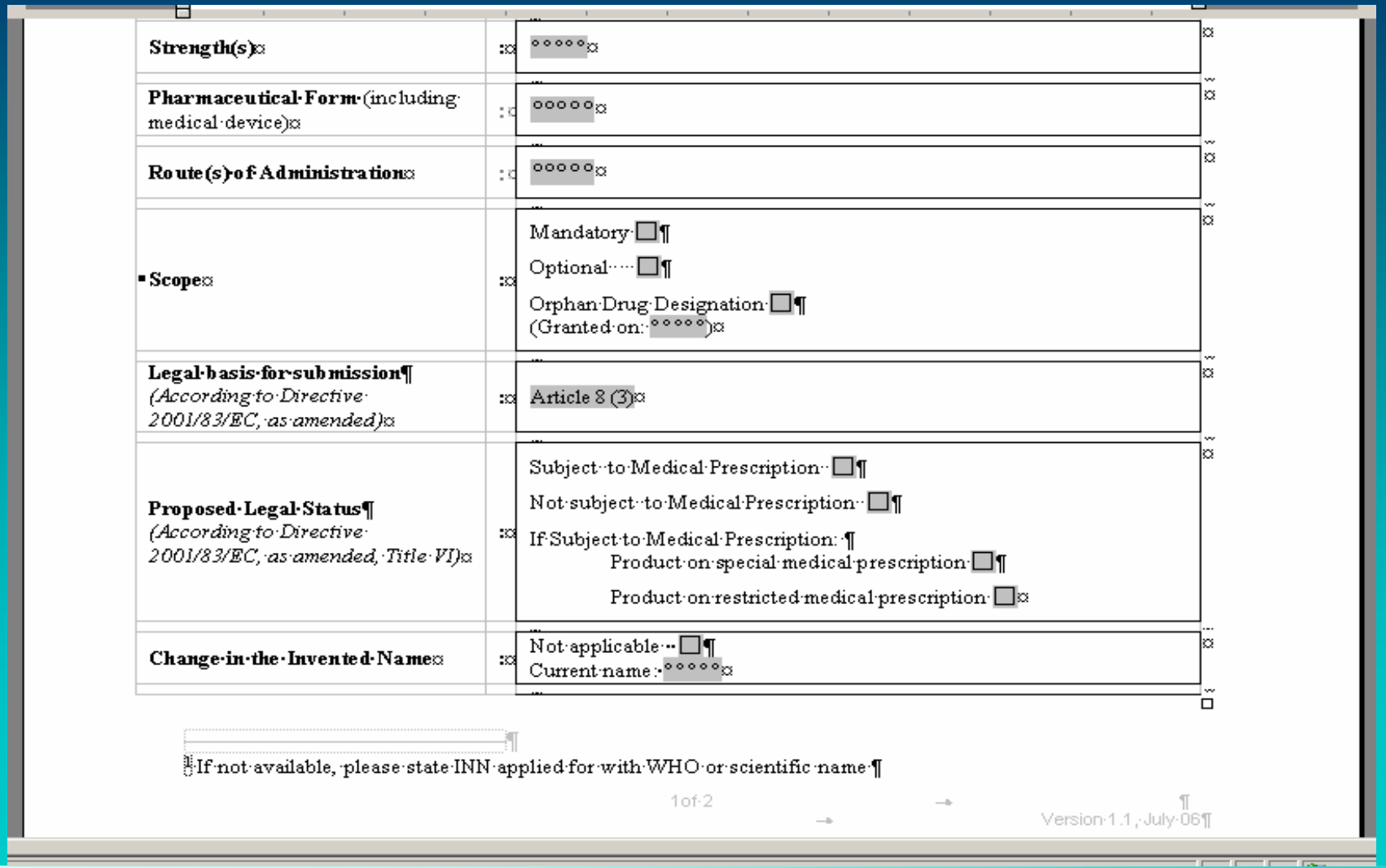
**Applicant's Details:**

| | |
|---|---|
| Applicant/ MAH Name | ooooo |
| Applicant/ MAH Address | ooooo |
| Contact Person Details (inc. Fax Number) | ooooo |

**Product information:**

| | |
|---|---|
| Proposed Invented Name | ooooo. |
| INN | ooooo./.ooooo |
| Intended Indication(s) | ooooo |

# JUSTIFICATION FORM – Proposed invented name(s)



| | | |
|---|---|---|
| **Strength(s)** | : | ° ° ° ° ° |
| **Pharmaceutical Form** (including medical device) | : | ° ° ° ° ° |
| **Route(s) of Administration** | : | ° ° ° ° ° |
| **Scope** | : | Mandatory ☐<br>Optional ☐<br>Orphan Drug Designation ☐<br>(Granted on: ° ° ° ° °) |
| **Legal basis for submission**<br>*(According to Directive 2001/83/EC, as amended)* | : | Article 8 (3) |
| **Proposed Legal Status**<br>*(According to Directive 2001/83/EC, as amended, Title VI)* | : | Subject to Medical Prescription ☐<br>Not subject to Medical Prescription ☐<br>If Subject to Medical Prescription:<br>Product on special medical prescription ☐<br>Product on restricted medical prescription ☐ |
| **Change in the Invented Name** | : | Not applicable ☐<br>Current name: ° ° ° ° ° |

If not available, please state INN applied for with WHO or scientific name

1 of 2

Version 1.1, July 06

# JUSTIFICATION FORM – Proposed invented name(s)

| | | |
|---|---|---|
| **Intended Submission Date** | : | |
| **Multiple applications[2]** | : | Not applicable ☐<br>Indicate number: |
| **Generic/ hybrid/ similar biological medicinal product** | : | Not applicable ☐<br>Reference medicinal product: |
| **Invented Names previously reviewed[3]/ outcome date** | : | |
| **Other relevant Information** | : | |

Justification to retain a non-accepted Invented Name:

| | | |
|---|---|---|
| **CHMP Outcome Date** | : | |
| **Detailed CHMP objection(s)** | | |
| **Justification(s) for re-submitting the Invented Name** | : | |

[2] Where proposed invented names are intended for use in the context of multiple marketing authorisation applications, the applicant shall specifically request the NRG to consider potential risks of confusing of these invented names with each other.

[3] For the same medicinal product

# Recommendations

- Include in your justification an assessment of potential for harm in case a mix-up would occur
- Need for establishment of common criteria and methodology for the conduct of “Prescription and interpretation studies and surveys”?
- Develop methodology concept with EFPIA?

# 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"

## Post-authorisation issues

- Change in (invented) name possible through a Type IB nr 2 after Commission Decision
- Including NRG letter of acceptance!

# NRG Procedure
# Checking invented names

**Other post-authorisation activities**

- Reporting of prescription errors/medication errors due to invented name in ADR/PSUR
- If not resulting in an ADR, the MAH and NCA should inform the EMEA
- With each PSUR, a summary report on medication errors, including due to name confusion should be submitted according to Vol 9 of NTA

# 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*

# Recommendations

- To avoid connotations of a cosmetic, food supplement or other products (e.g. Sun...)?
- To avoid ‘known’ words in the names (e.g. can do)?
- To avoid using misleading terms (e.g ‘MR’ for a prolonged release form)?

# 4 – Criteria addressing INN/INN stem concerns in proposed invented names

# Recommendation

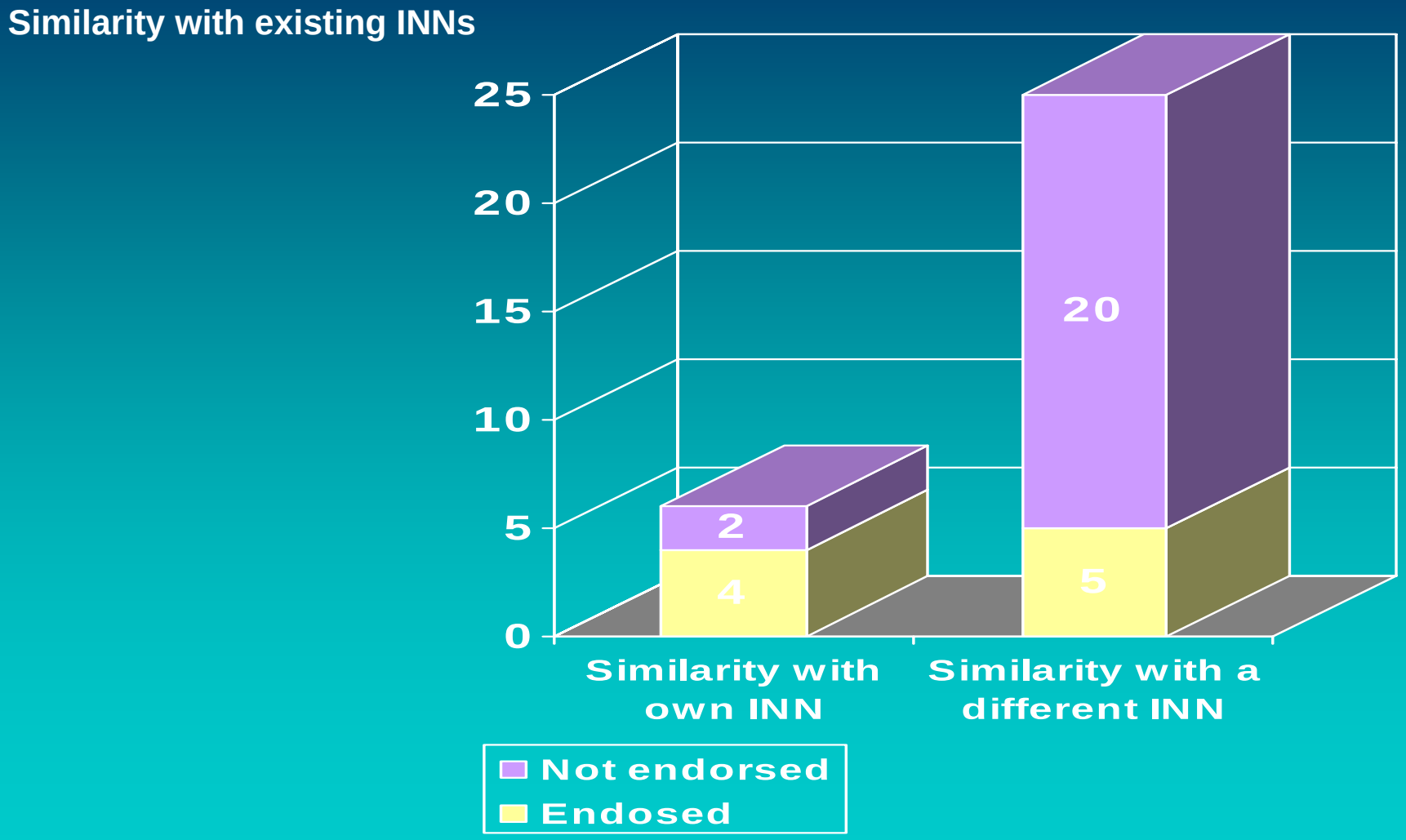
- Applicant/MAH to undertake
  - Review of similarities with existing INNs and INN stem inclusions prior to submitting their proposed invented names
  - Address any issues arising from the above in the application form or provide a justification for deviation

# INN/INN stem related information - WHO website -

Links:

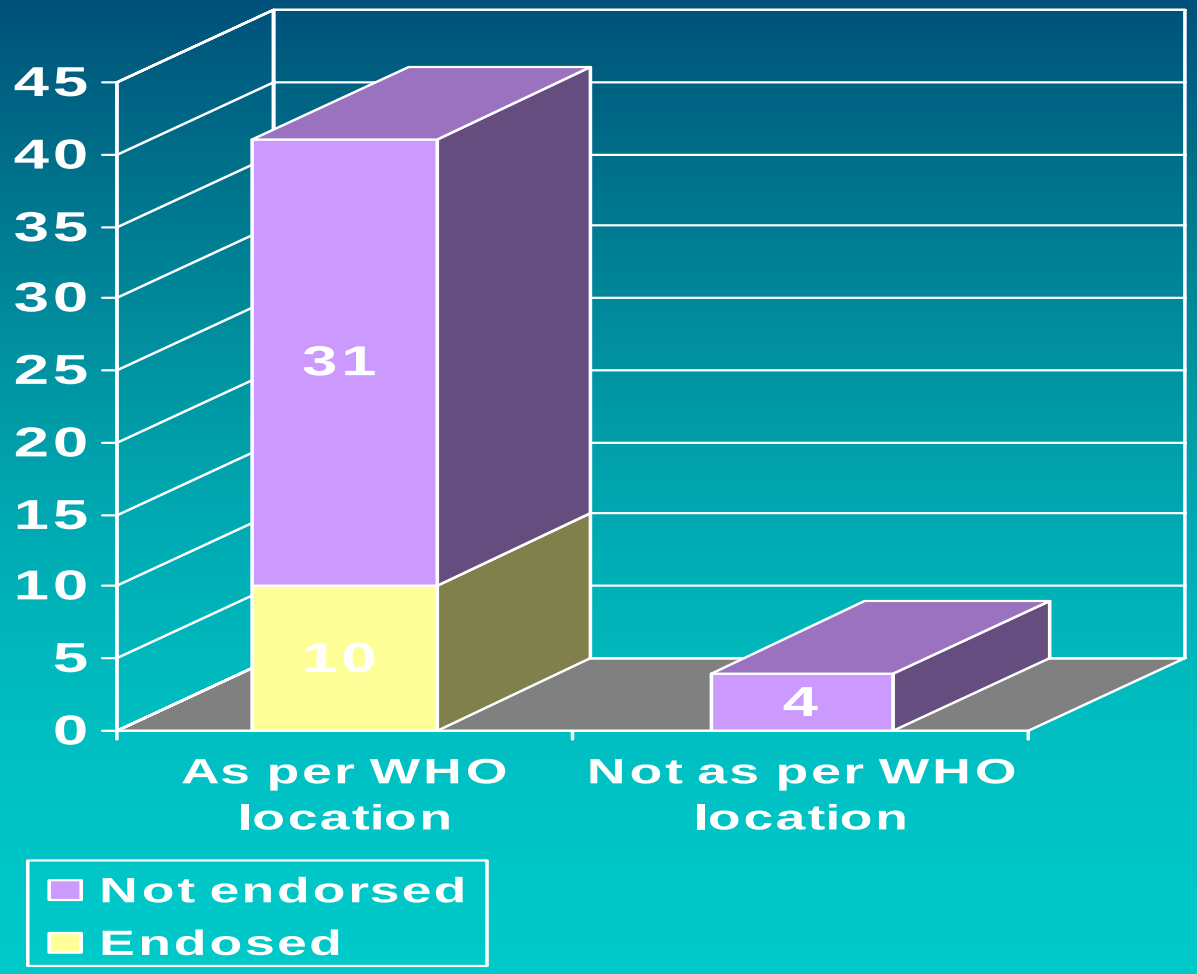
- http://www.who.int/medicines/services/inn/guidamce/en/index.html
- http://www.who.int/medicines/services/inn/generalprinciplesEn.pdf
- http://whqlibdoc.who.int/hq/2004/WHO_EDM_QSM_2004.5.pdf

# INN related objections
# Since July 2004



# INN stem related objections Since July 2004

Inclusion of INN stems



# 5 – Criteria addressing other public health concerns

# IN Guideline criteria
# - Other public health concerns -

Current guideline (revision 4) restrictions

1. Preferably one word. The use of short qualifications/abbreviations which do not carry an established and relevant meaning in all Member States, is unacceptable. […] . Descriptive abbreviations if need to distinguish route of administration (e.g. IM, …)

# IN Guideline criteria
# - Other public health concerns -

Current guideline (revision 4) restrictions

2. Not convey any promotional message with respect to the use of the product (e.g. Plus).
3. Not appear offensive or have a 'bad' connotation in any of the languages.

# IN Guideline criteria
# - Other public health concerns -

Current guideline (revision 4) restrictions

4. Use of capitals in invented name should reflect the proposed/approved trademark registration.
5. IN for fixed combinations should be completely (?) different from the IN of individual active ingredients.

# IN Guideline criteria
# - Other public health concerns -

Current guideline (revision 4) restrictions

6. IN for prodrug different from the medicinal product borne by related active substance.
7. IN for Annex II applications same except for justified qualification/abbreviation
8. Requirements for vaccines, biological and orphan medicinal products

# Recommendations

- Loss of time to submit names which are not in line with the guideline, unless accompanied by a sound justification?
- If deviation, not useful to submit 4 different names with e.g. same qualifier? → erroneous NRG statistics

# Recommendations

- Confirmation sought on whether similar names between Fixed Combinations and individual Active Substances or between names of Fixed combinations for similar indication are indeed a risk to public health or on the contrary helpful?

# 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

# 7. Transparency

# 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

**Post-authorisation Guidance: Q/A on invented names** NEW

**Guideline on acceptability of the invented name**

# Transparency

CHMP Monthly report NEW

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

Annual report

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

# CHMP Monthly report – Annex 7 Example

ANNEX 7 TO CHMP MONTHLY REPORT MAY 2006

**Name Review Group (NRG)**

| | May 2006 | | | 2006 | |
|---|---|---|---|---|---|
| | Accepted | Rejected | Pending | Accepted | Rejected |
| Proposed invented names | 22 | 23 | 29[1] | 47 | 74 |
| Justification for retention of invented name * | 3 | 0 | 11[2] | 5 | 13 |

*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 EMEA website.

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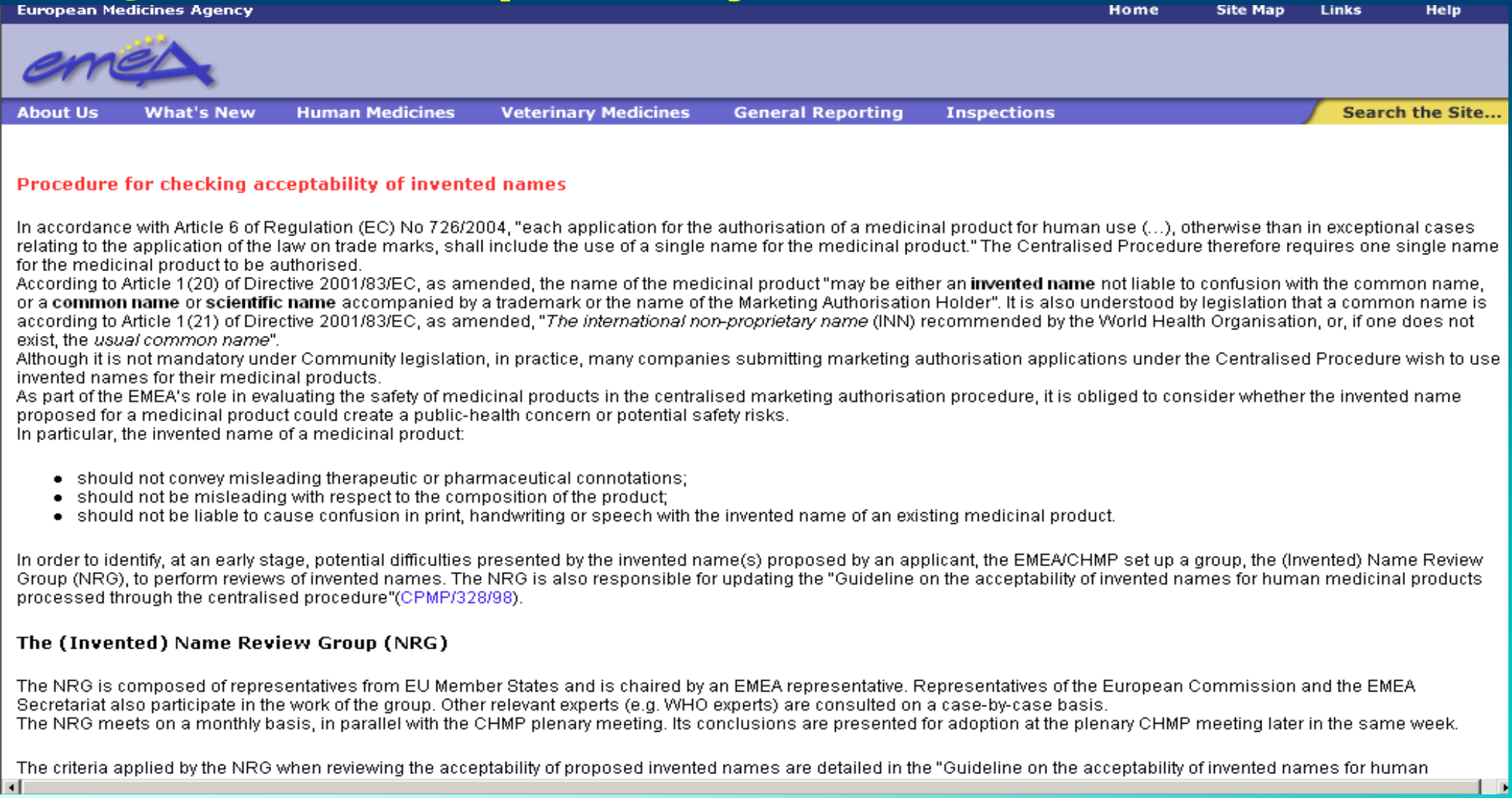
[1] Two proposed invented names requests have been postponed from the May NRG meeting.
[2] One justification request has been postponed from the May NRG meeting.

# Pre-submission Guidance
# Q/A on acceptability of invented names:



# Pre-submission Guidance
# Q/A on acceptability of invented names:

**EMEA procedure for checking proposed invented names**

- Submission of the invented name request by the Applicant/MAH

Provided that the medicinal product is eligible for evaluation under the Centralised Procedure, the applicant should inform the EMEA of the proposed invented name(s) for their medicinal product at the earliest 12 months and preferably 4-6 months prior to the planned submission date of the marketing authorisation application. See also the deadlines for submission of Proposed Invented Names.
The 'Proposed Invented Name Request form', along with either a draft Summary of Product Characteristics (SPC) or a product profile, should be sent to the EMEA at the e-mail address: NRG@emea.eu.int.
The applicant is advised to propose up to four invented names per marketing authorisation application indicating its preference, if any, so that the acceptability of a 'back-up' invented name can be considered without loss of time.
Applicants should follow the criteria described in the 'Guideline' when proposing invented names. Where the applicant deviates from these criteria, justification should be provided.
Where the applicant submits proposed invented names intended to be used in the context of multiple marketing authorisations/applications it shall specifically request the NRG to consider whether the proposed invented names cannot be considered potentially confusing with each other (see also question on Multiple Applications).

- Consultation with the Member States and WHO and NRG discussion/CHMP adoption

The proposed invented name(s) and all the background information provided by the applicant(s)/MAH(s) are sent to every NRG contact point nominated by National Competent Authorities (NCAs) of EU Member States, the European Commission (EC) and the World Health Organisation (WHO) for their review and will subsequently be discussed at the NRG meeting. The detailed procedure is described in the 'Guideline'.
The NRG conclusions/recommendations are presented for adoption to the subsequent CHMP plenary meeting, after which the applicant will be informed of the outcome of the discussion on the acceptability of the proposed invented name(s) for their medicinal product together with the reasons and source for the objections(s) raised, where applicable. See also the dates of NRG discussion/CHMP adoption.

- Rejection by NRG/CHMP of a proposed invented name

In case of rejection of a proposed invented name by NRG/CHMP, the applicant/MAH has got the following possibilities:

1. To submit new invented names proposals, which are checked through the same procedure as described above.
2. To provide a justification to retain the invented name (addressing specifically all the objections raised) using the 'Invented Name Justification Form'. Such justification will be reviewed as described in the 'Guideline'. If the proposed invented name cannot be accepted prior to submission, the Marketing authorisation application can be submitted under either any of the proposed invented names or the common name or scientific name accompanied by a trademark or the name of the MAH.

At the latest one month prior to the adoption of the CHMP opinion on the concerned MAA, the applicant will in such case have to inform the EMEA and the NRG Secretariat on the acceptable invented name of their choice.

1. In the event no invented name is accepted prior to adoption of the CHMP opinion, the Applicant will obtain its medicinal product opinion adopted under the common name or scientific name accompanied by the name of the MAH. In such a case, as soon as the Commission Decision is granted, the MAH may submit a variation to introduce an invented name, on the condition that such name has been considered acceptable by the NRG.

# Pre-submission Guidance
# Q/A on acceptability of invented names:

2. Exceptionally, provided *all means have been exhausted*, the applicant/MAH may request the matter to be presented to the CHMP within the context of the evaluation of the medicinal product (e.g. oral explanation).

- Change of the invented name after the marketing authorisation is granted

In accordance with Commission Regulation (EC) No 1085/2003 as amended, the (invented) name of a medicinal product may be changed after a marketing authorisation is granted through a Type IB (No.2) variation procedure.
Such variation application should be submitted in accordance with the procedure described in Article 5 of Commission Regulation (EC) No 1085/2003, for Type IB variations and the conditions described in the Annex I to the same Regulation (see also EMEA post-authorisation guidance). Taking into account that the MAH will be required to submit the EMEA letter of acceptance of the concerned invented as part of the variation application, it is recommended that the proposed invented name be submitted at least 4-6 months in advance of the intended Type IB (No.2) variation application.

**References**

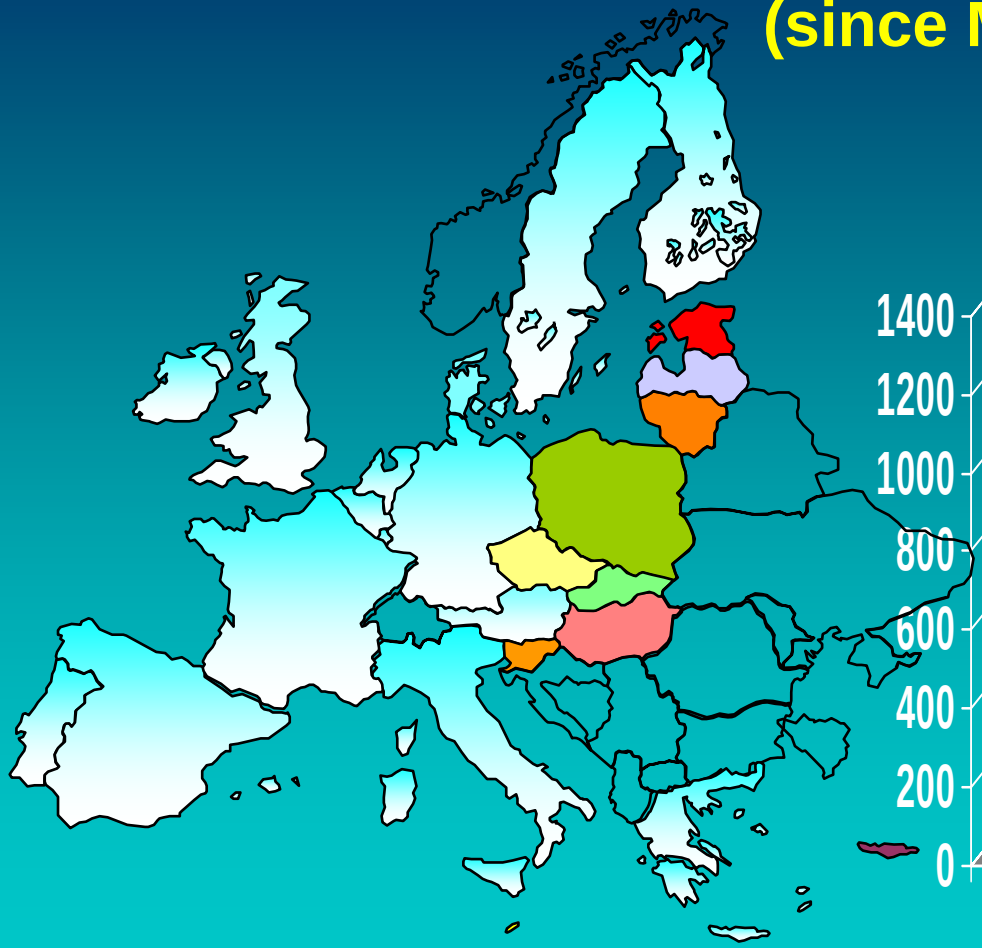

- Regulation (EC) No 726/2004
- Directive 2001/83/EC, as amended
- "Centralised Procedure", the Rules governing Medicinal Products in the European Community, Notice to Applicants, Volume 2A, Chapter 4
- "Guideline on the acceptability of invented names for human medicinal products processed through the centralised procedure"(CPMP/328/98)
- Regulation (EC) No 1085/2003

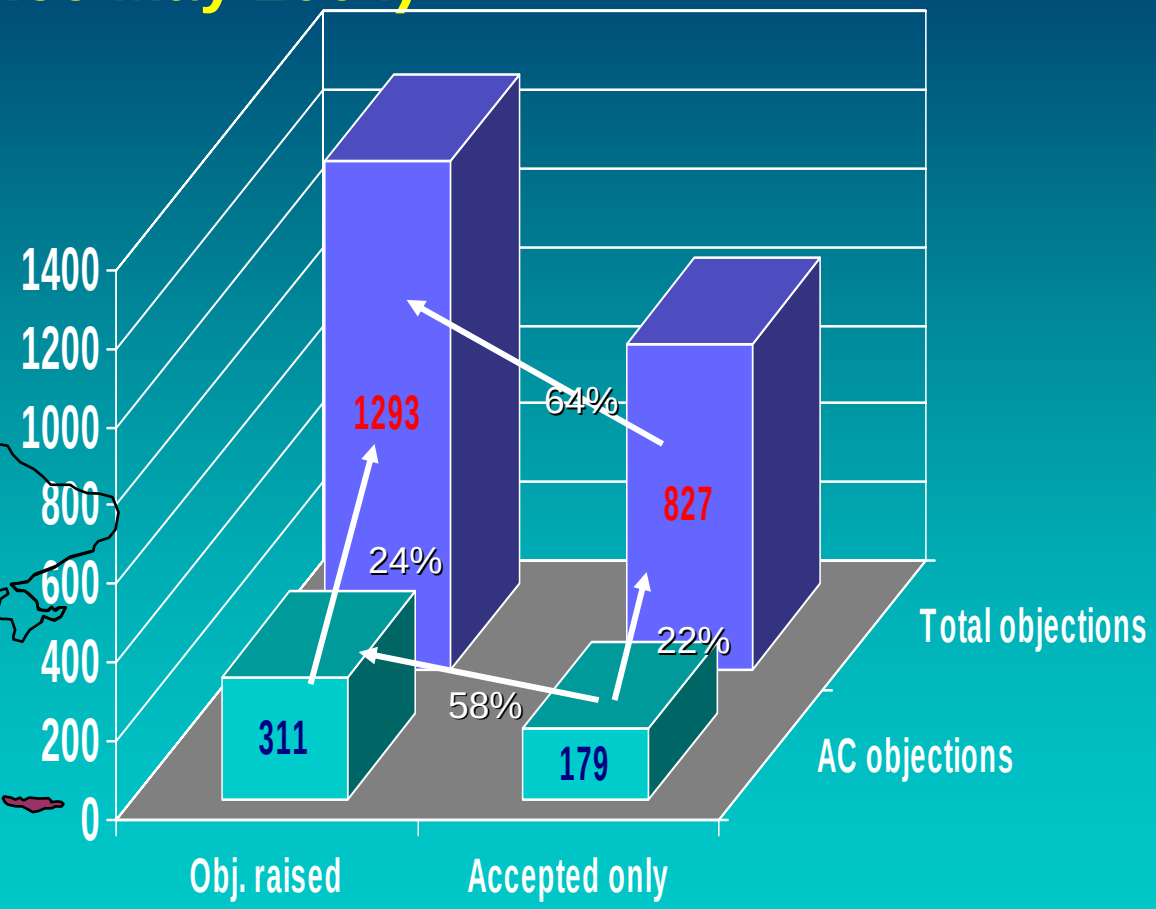
# 8 - INs & Enlargement :

# Review of invented names by Bulgaria and Romania

# Proportion of objections by 10 'New' Member States

(since May 2004)





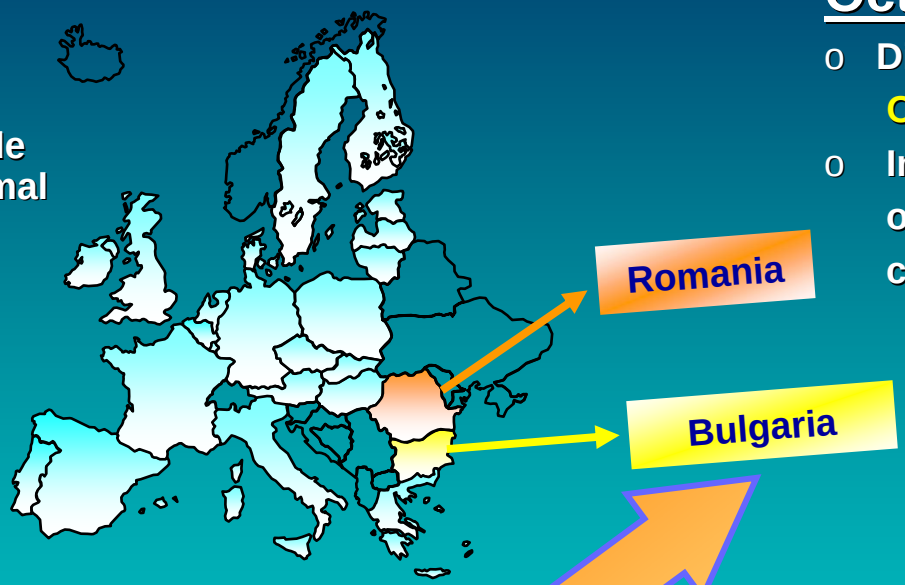
# IN Review by Bulgaria & Romania

## April '06

Request HoA to nominate:

- NRG Contact point
- Observers/Members to NRG

[Participate and provide comments but not formal objections]




## October - November '06

- Discussion of objections at Oct – Nov 2006 NRG
- Inform companies on the outcome through national competent authorities

## June/ August '06

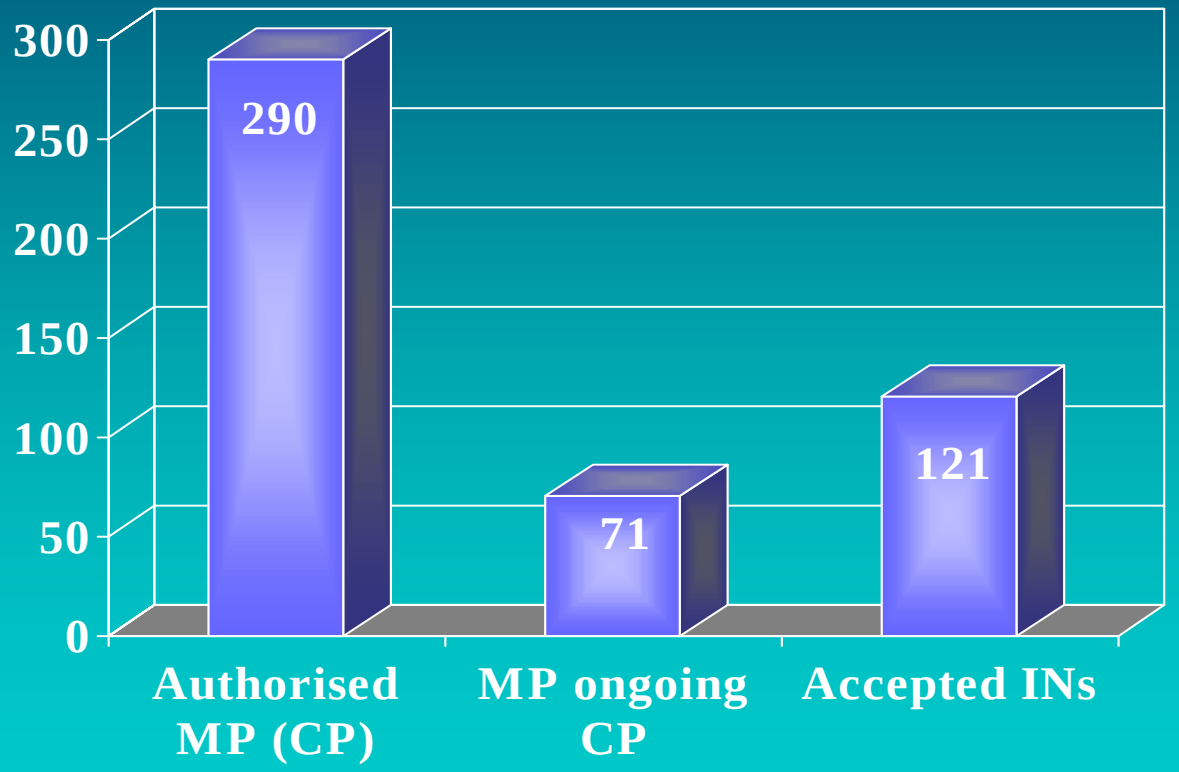
- RO participation to June NRG meeting
- 10 Aug 06: Listings of invented names of MP centrally authorised / pending authorisation and all NRG accepted names (excluding above) for the period of 01/2005-07/2006)
- Sent to RO and BU for review by 5 Oct 06

## By January '07

Remaining issues solved by accession

# Review of Invented Names by Accession Countries

**Total Invented Names reviewed : 482**

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# THANK YOU !