EMEA MEETING WITH INTERESTED PARTIES

On the Review Process on Names for Medicinal Products

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Presentation by EFPIA

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1. OBJECTIVES OF THE DAY

Following-up from our first Meeting in 2001, continue our dialogue towards reducing the rejection rate of Invented Names (IN) while ensuring European patients' health & safety through:

. a better understanding of the EMEA/ CHMP/ NRG procedures

. a greater certainty in the name approval process: ensure that consistent objective and more predictable criteria are used and deadlines complied with

2. THIS PRESENTATION

Aims at obtaining clarifications on:

A. Exceptions to single trade mark rule
B. Transparency of decisions by CHMP/NRG
C. Avoidance of confusion with INNs
D. Raising of objections and appeal procedure

3. SETTING THE CONTEXT

The complex, lengthy and costly process of creation and choice of trade marks for pharmaceuticals, including safety testing, have been explained during the Workshop with the NRG

4. INDUSTRY'S ISSUES OF CONCERN

A. Exceptions to single trade mark rule

Background

- **For the first time, requirement for a single name for a centrally authorised medicinal product is codified,**

- **as well as the possibility of derogations "in exceptional cases relating to the application of the law on trade marks"**
  (Regulation N°726/2004, Guideline & Communication).

Our understanding

When preparing a trade mark for a centrally approved product, if it is not possible to obtain our trade mark in the 25 EU countries (+ Norw + Iceland), we may ask the Commission for a derogation

Our question

But when? We prepare the TM 2 to 5 years before the application of the MA. We strive to secure a global brand name and not only for Europe.

Our concern

When we submit our name(s) to the NRG, those names are generally already registered as trademarks in the 27 countries.

500 names created to be able to present 3.

62, 5% of the names are rejected by NRG: from EMEA's perspective the invented name might present a safety risk for patient.

This high rejection rate is not linked with legal TM issues.

Our common objective is how to reduce the high rate of rejection.

In the Guidelines when considering exceptional cases, you refer " in particular" to trademark cancellation, opposition or objection.

In the Commission's Communication [1] (1998)

"…Only one brand name should normally be approved per marketing authorisation granted".

-"…However in exceptional cases, in particular where the proposed brand name has been cancelled, opposed or objected to under trade mark law in a MS,…,

…If sufficient evidence is given by MAH that, in spite of all its efforts, the chosen or foreseen trade mark cannot be used in a MS, the Commission will- exceptionally- authorise the use of a different trade mark in that MS"

This means there is room for other basis for exceptions.

[1] Communication 98/C 229/03 dated 22/08/1998, Official Journal C229/4 of 22/07/1998

What is the justification for the Single Trade Mark

- **free movement of goods**
- **no safety reasons**

The STM rule was introduced to facilitate free movement of pharma products within the EU, not for safety reasons. There is no evidence that using different trade marks would partition the market (see ECJ rulings allowing to change the name of the trade mark of a parallel imported product and confirming that no partitioning ever occurred in the framework of the mutual recognition procedure).

ECJ Case law clearly allows exceptions to the STM rule other than those stemming from trade mark law.

"The Commission may authorise the adding of a name to a Community MA **where:**

1. ***there exist exceptional circumstances which may adversely affect public health,***

2. ***and the variation applied for satisfies the criteria of quality, safety and efficacy of the medicinal product (§79)"***

(from Dr Karl Thomae Case (T-123/00), Judgement of 10/12/2002)

If Industry has in MRP (Mutual Recognition Procedures) adopted Trade Marks that could differ in the EU countries it is either because of :

- **Reasons linked to Trade Mark law (prior TM rights)**
  ex: ATACAND in EU → RATACAND in Italy,
  AVELOX in EU → AVALOX in Germany and Italy

- **Phonetic, linguistic, grammatical reasons or negative connotations**
  LOSEC in EU → MOPRAL in France (meaning l'eau sec),
  LOCABIOTAL in EU → FUSALOYOS in Spain (loca means crazy)

- **A request from the Health Authorities**
  CIPROXIN in EU → CIFLOX in France,
  AVELOX in EU → IZILOX in France

INNs variations are considered as being one name, the same should apply to invented names in case a slight variation is proposed

Ex. for **INN** :	ibandronic acid	(in English)
	acido ibandronico	(in Spanish)
	acide ibandronique	(in French)
	ibandronihappo	(in Finnish)
	ibandroninezuur	(in Dutch)
	ibandronska krislina	(in Slovenian)

Ex. for **TM** : FRAXIPARINE / FRAXIPARINA
GLEEVEC / GLIVEC

Conclusion:

It should be reasonable to allow flexibility with respect to the single trade mark rule where this would meet the interests of Patients, EMEA and the Companies.

Proposed solutions for flexibility

Issues due to TM law

Industry will ask the Commission for a derogation

- When? Could it be before submitting the name to the NRG?
- What kind of TM conflicts? Refludan / Refludin = a refusal of coexistence
- At which stage of the legal procedure?

We submit that it should be possible when a litigation is pending or threatened

Proposed solutions for flexibility

Other circumstances
(linguistic, phonetic, conceptual or safety reasons)

To overcome an objection from NRG

→ **Applicant proposes slight variation of the invented name in a MS**

→ **Slight variation is sufficient to overcome the risk identified by the NRG**

→ **EMEA should have the possibility to accept the variation if as a result the name is safer for patients**

→ Slight variation is <u>not</u> sufficient to overcome the risk identified by the NRG

→ The new name is not considered as a variation but as a different name and a derogation should be requested from the Commission

Slight variation should be considered to be the same name (as for INN linguistic variations)

4. INDUSTRY'S ISSUES OF CONCERN (ctd)

B. Transparency of Decisions by CHMP/"NRG" (point 5 of EMEA Guideline):

Answers to our Questions would be helpful

- **How are Invented Names evaluated locally?**
- **Which databases are used locally?**
- **Which methods are used locally to evaluate names?**
- **On what grounds are objections raised: Are the different criteria applied in a harmonised way?**

- **Difficulty: Name submitted, objections received, new objections are raised at later stage**

- **Consequences:**

  For industry, despite submitting a name up to 12 months before filing the Marketing Authorisation Application, the process is still full of uncertainties until a very late stage, inducing extra costs and delays that may even postpone product launch to detriment of patients

Conclusion: Improved transparency would offer greater predictability and more certainty

4. INDUSTRY'S ISSUES OF CONCERN (ctd)

C. Avoidance of Confusion with INNs
(point 3 of EMEA Guideline)

Caution with overly broad WHO Resolution [1] whose literal application would cause the loss of at least 25% names.
Also, risk of contradictory decisions at national and centralised levels.
Industry accepts that established INN stems without further elements should not be used as names but flexibility to use non stem part or stem part of INN is acceptable for safety reasons under certain conditions:

[1] WHA Assembly requests MS to … discourage the use of names derived from INNs, and particularly names including established INN stems as trade marks

Examples

1/ Some stems are very simple: one syllable only:

- ac - ium - tide - ur

There already exist numerous trade marks in the market containing those stems, including in a stem position.

Ex. : Prozac, Zantac, Parfenac, Idarac, Dermofenac, Ranzac, Slofenac, Zorac, Defanac, Salatac, Loxapac, Celevac
Motilium, Imodium, Palfium, Celnium, Cleridium, Protium, Librium ….

To exclude those stems in an invented name limits considerably the creation of new trade marks, without real safety justification as those syllables are very common in all EU languages and not therapy specific.

Suggestion: A more specific list of INN stems strictly prohibited would be more than welcomed or at least the possibility to use short stems

2/ Use stem part of INN but in a non stem position, should be acceptable

Examples : - arit (anti-arthritic substances) :
CLARITYN, VARITAN, TARITUX

3/ It should be possible to use any part of the INNs which do not constitute a stem, independently of whether it belongs to the same or a different therapeutic class.

Ex. INN : LEXOFENAC (stem: -ac)
TMS : LEXOMIL, LEXOTAN

Conclusion: We encourage flexibility to use non stem and stem part of INN under the conditions mentioned above.

D. Raising of objections, NRG decisions and appeal procedure

- **Industry would appreciate the possibility of having a dialogue through direct exchanges or face-to-face meetings or to submit for appeal a decision by the NRG to find a suitable solution**
- **Could the decisions by the NRG be adopted by so-called "super majority" (e.g. 90%)?**

Conclusion: Details on grounds for objections needed in all cases

Discussion at different levels would certainly help reducing the current high rejection rate of invented names

We look forward to pursuing our cooperation with the NRG and NCAs towards our Common Objective of Ensuring European Patients' Health & Safety

WE THANK YOU FOR YOUR KIND ATTENTION

AND WILL BE HAPPY TO ANSWER YOUR QUESTIONS!

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