Name Variations:

A Proposal for Increased Flexibility under the EU Single Trade Mark Requirement

Joint EMEA (NRG)/EFPIA Workshop

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1. Overview

- Introduction and Objectives
- Historical Background
- The *Karl Thomae* Case
- Position under Regulation 726/2004
- Scope of ‘Exceptional Cases’
- Use of different names is already permitted
- Minor variations of an invented name
- Objections raised during the EMEA evaluation
- EFPIA’s Proposal

2. Introduction and Objectives

- Reg. 726/2004, laying down procedures for authorization and supervision of medicinal products replaces Reg. 2309/93
- Reg. 726/2004 has codified requirement for single name for medicinal product authorized through centralized procedure
- Objectives:
  - to explain why concept of ‘single name’ should be interpreted flexibly, to include minor variations of name
  - propose procedure for granting derogations to single name requirement

3. Historical Background

- Commission practice developed under Reg. 2303/93 for centrally approved product:
  - single SmPC
  - single PI leaflet,
  - single approved label

  distributed under single trade mark (STM)
- Commission communication, 22 July 1998 set out circumstances in which derogation to STM permitted
- In ‘exceptional cases’ where chosen STM could not used in a Member State, Commission would authorize use of a **different** trade mark in that Member State

3. Historical Background

- Two derogations permitted:
  - REFLUDAN/REFLUDIN (Hoechst)
  - INFERGEN/INFERAX (Yamanouchi)
- In each case, applicant for MA required to present sufficient evidence that ‘in spite of all its efforts’ the applicant would not be able use chosen trade mark in Member State
- Hoechst case concerned Spain
- Yamanouchi concerned Spain and Germany

4. The *Karl Thomae* Case

(T-123/00)

- Karl Thomae wished to use different names DAQUIRAN/FIROL/SIPNOK on centrally authorized product
- In annulling decision of EMEA rejecting application, CFI observed that:
  - in context of MRP, one medicinal product may lawfully have names which vary from on MS to another
  - no grounds for concluding that different names cannot be used where MAH shows 'rendered necessary by exceptional circumstances which may adversely affect public health'
  - consonant with Commission communication of July 1998
- Commission acknowledged that use of different names for same product in community does **not** give rise to any specific risks for public health

5. Position under Reg. 726/2004

Art 6 requires:

'otherwise than in exceptional cases relating to the application of the law of trade marks' an application for a community authorization for a medicinal product *'shall include the use of a single name for the medicinal product'*

- Existing derogations remain in force: Art 6 must apply to these
- Apparent that Commission communication is appropriate for dealing with new 'exceptional cases'
- MAH/applicant presents 'sufficient evidence', Commission then authorizes use of different mark

6. Scope of ‘Exceptional Cases’

- According to Reg. 726/2004, STM required except for cases ‘relating to application of trade mark law’
- Commission communication broader:
  - ‘**particularly** where the proposed brand name has been cancelled, opposed or objected to under trade mark law in a Member State’
- Could include:
  - Health and safety concerns raised by EMEA
  - Pejorative connotations in one or a few Member States
  - Other reasons to be agreed by the EU Commission

7. Use of different names already permitted

- Art 82(1), Reg 726/2004 permits more than one application for a specific medicinal product when there are objective verifiable reasons relating to public health, eg:
- Duloxetine medicinal products:
  - YENTREVE for stress incontinence in women
  - CYMBALTA for major depressive episodes
- or co-marketing reasons:
  - PLAVIX
  - ISCOVER
- No evidence that different names gives rise to risks to public health

7. Use of different names already permitted

- Unique nature of Community authorization is determined not by name, but documents characterising medicinal product, annexed to favourable opinion, such as SmPC
- As the CFI noted in *Karl Thomae*, the aim of Community law in this area is to bring about the free movement of medicinal products within the Community, whilst ensuring that public health is protected.
- Issues relating to acceptability of invented names should not delay access to medicines
- Accordingly, Commission should agree to derogation before EMEA gives CPMP opinion

8. Minor variations of an invented name

- INN in different languages exist in different versions
- Under Art 3(3)(c), Reg 726/2004, all linguistic versions considered to be same INN, e.g., ibandronic acid:

ES:	acido ibandronico	NL:	ibandroninezuur
DE:	Ibandronsäure	SE:	ibandronatsyra
FR:	acide ibandronique	DK:	ibandronsyre
FI:	ibandronihappo	SL:	ibandronska krislina

- Minor variations of the invented name should be considered same name

8. Minor variations of an invented name

- Variations in invented names have been used for years under national regimes, with no sign of risk to patients, in one case (GLEEVEC /GLIVEC) even requested by the Health Authorities,
- Phonetic reasons:
  - OPTICROM/OPTICRON
  - FRAXIPARINE/FRAXIPARINA
- Linguistic reasons:
  - BUSCOPAN/BUSCAPINA
  - STILNOX/STILNOCT
- Such variations should be considered as **same name**

8. Minor variations of an invented name

- For invented names to be considered the same, variations should maintain sufficient common elements to indicate that they are intimately related.
- In general, will mean that names will differ by no more than a few letters or in a single syllable.
- Minor variations in invented name do not interfere with the unique, Community nature of the authorisation
- Should be allowed *de facto* by EMEA under existing legislation and considered to be **same name**.

9. Objections raised during EMEA evaluation

- Invented names review by NRG in accordance with Guidelines, CPMP/328/98
- According to Guidelines, the invented name of a medicinal product:
  - should not convey misleading therapeutic or pharmaceutical connotations;
  - should not be misleading with respect to the composition of the product;
  - should not be liable to cause confusion in print, handwriting or speech with the invented name of an existing product.
- Existing product will often – but not always – be subject of earlier TM registration

9. Objections raised during EMEA evaluation

- EMEA is not concerned with TM rights and infringement
- EMEA frequently objects that proposed name is confusable with name of existing product
- When NRG objects in such circumstances, applicant for MA, minor variations in invented name should be allowed *de facto* to avoid potential confusion and therefore risk to public health

10. EFPIA's Proposal

- Minor variations in an invented name to be considered to be the **same name** and constitute a single name for the purposes of Art 6, Reg 726/2004
- Can be proposed by MA applicant after submission to resolve risk of confusion
- Minor variations maintain sufficient common elements to show names intimately related
- Should be accepted *de facto* by EMEA
- Policy in derogations for **different name** to follow Commission communication of 22 July 1998
- To avoid delay, derogations to be approved by Commission before CPMP opinion