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European Federation of Pharmaceutical Industries and Associations

Implications of the EMEA Naming Policy
An Industry Perspective

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1. Importance of the EMEA Naming Policy

- Patient Safety and Patient Access to Medicine is a shared interest between Industry and EMEA.

- A constructive and fruitful EMEA-EFPIA dialogue has been established through regular Interested Parties- and Workgroup meetings, guiding a unique collaboration for patient health & safety of names

2. Cornerstones of the EMEA Policy Naming Policy

- The Invented Name is an integral part of the CP NDA process
- Current pharmaceutical legislation requires a single name across the EU
- Defined clearance process available
- Naming guidelines and evaluation process – advanced Revision V implemented in 08
- Constructive EMEA-EFPIA dialogue

2.1 Impact of Legislation: Single Trademark Requirement

Regulation (EC) No 726/2004, requires a single trademark "otherwise than in exceptional circumstances relating to the application of the law on trade marks."

- Industry strives for EU wide / global names
- No flexibility to adjust a name, e.g. with a minor variation in certain member states, in the event that issues relating to risk of confusion with an existing medicinal product are raised during the EMEA review.
- Accession of new EU Member States lead to a significant rise of name rejections based on such potential risks raised in one or few member states.

2.2 Implications of the EMEA Name Clearance Process

- Transparency on NRG meeting schedule and statistics "online"
- Flexibility through simultaneous review of up to 4 names
- Rapid feedback within 3 months

- Option to submit justification for a rejected name = opportunity and challenge

- Potential for late stage rejections, preserving the possibility to reject the name closer to or after granting of the MA.

3. Importance of a global Trademark ® protected Invented Name

- Unique and protected identifier of origin
- Identifies product as coming from a trusted source

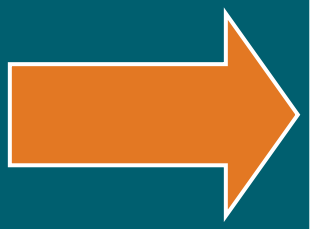
- Globally protected names support globalized environment, e.g. travel / internet

- Trademarks can add to name safety
  - Support identification of counterfeits
  - As being more differentiated vs. INNs
  - Trademark clearance and continuous enforcement ensure „space“ around a name is protected throughout lifetime.

3.1 Trademark Selection:
It's just a name, how hard can it be?

European / Global Trademarks must meet ALL criteria below:

- Appropriate Marketing Vehicle
  = short, distinct, memorable
- Registrable at Trademark Offices Worldwide
  = crowded TM registers for pharmaceuticals, drop out rate ~ 94%
- "Safe" and Acceptable to Health Authorities Worldwide
  = 40-50 % rejection rate globally, predictability of name approvals, reduced flexibility for minor variations under Single TM Rule in EU



+ 500 names are created in order to find 3-4 names that fit all of the criteria above!
The process takes approx. 3 years.

3.2 Managing the EMEA Naming Evaluation

- Need to build cross functional know how and processes
  - E.g. project teams with Trademarks, Development, Drug Regulatory Affairs, Marketing, Technical Operations / Production / Logistics
- Provide significant people- and financial resources
  - E.g. invest in prescription error testing with Health Care Professionals and expert panels
- Optimal process to identify name safety risks while predictability remains a challenge?
  - E.g. test in larger countries and make internal name assessment in all member states through own local regulatory experts

3.3 Managing Name Rejections

- Require risk management procedures put in place
  - E.g. have back-up names ready
  - reconsider global name
  - parallel packaging/material production for launch
  - short term priorization of resources to prevent launch delays/ delayed patient access to medicine
  - Managing company expectations and communication
- Manage name reassessment option – provide justifications
  - Potential for patient harm analysis
  - Verify status of conflicting product/use
  - Side by side comparison from “procurement through administration“
  - Build know how and resources
- Manage Trademark implications of name rejections
  - Potential for more crowded TM registers and more complex names
  - EMEA decisions can trigger approval for use of invented names conflicting with TM legal priority – timing challenge

4. Achievements and Progress in EMEA Naming Policy

- Revision V of the Naming Guidelines:
  - Removal of two a priori restrictions: modifiers and similarity of fixed combo names to mono compound name
  - INN decision tree
  - Acknowledgement of perceived risk vs. increasing complexity of names

→ Positive increase of name approval rate from 32% in 05 to 62% in September 08

- Work in progress:
  - Standards for national name assessments and harmonization of rules
  - Reservation of precleared names to avoid late stage rejections and delayed patient access to medicine

→ Persisting challenge of predictability of name approvals and cause-effect relationship of names to medication errors

5. Outlook on continued EMEA-EFPIA Dialogue

- Increase predictability of name approvals
- Clarify the cause effect relationship of names to medication errors, e.g. monitoring / legibility impact, etc.
- New trends, e.g. fixed combo families, share insights from patients / physicians
- Reservation of precleared names
- Acceptable Modifiers, Paediatric Modifier, support documentation
- Harmonization of name assessment rules for suspended, revoked, withdrawn products

- Thank you