



Regulatory challenges when clearing trade marks in the pharmaceutical sector

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Summary

- Challenges for the pharmaceutical industry
- Regulatory hurdles
- Managing name rejections

Challenges for the pharmaceutical industry

- TM creation mostly starts in late Phase II of clinical drug development
- Duration: it takes approx 3 - 4 years to generate and register a trademark globally for each compound in development
- 100-150 names are created to have one main mark and 2 backups
- Average trademark searching and prosecution costs per global TM creation project from generation through to registration ranges from 250,000 – 1,000,000 Euros

TM registrations vs unregistered TMs

- In some jurisdictions it is a requirement to have a trademark registered in order to apply for the marketing authorization.
- TM Registrations are the best instrument to fight against counterfeits.
- Easier to remember than INNs.
- Regulatory Authorities can approve invented names conflicting with earlier trademarks – timing challenge

What makes a good name? It depends on who you ask...

- Trademark Offices
 - Is not “confusingly similar” to other trademarks, is not descriptive
- Health Authorities
 - Cannot be confused with another drug name when prescribed, dispensed or administered
- Marketers
 - It depends...and all of the answers are correct!

Five Major Hurdles in chronological order

1. Market suitability/Global Brand concept
 - briefing, selection, customer insights and taste
2. Global Cultural/Linguistic suitability
3. Global Registration at “Trademark offices”
 - Crowded TM/DN Registers, drop out rate 94%
4. Safety and Health concerns at EMEA and FDA (CAN, Jap.)
 - 40% rejection rate
5. Single trademark requirement at the EU Commission for products approved via Centralised Procedure
 - 27 countries

Obtaining a trade mark through the centralised procedure - EMEA

- Products approved by the Centralised procedure require **ONE** trade mark that is acceptable to all Member States.
- Products covered by the centralised procedure include oncology, AIDS, neurodegenerative disorders, diabetes, designated orphan medicines and vaccines.
- Exception Article 6 Regulation 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.”

Rejection rates at EMEA and FDA



- 40% of all names submitted for FDA approval are rejected



- 43% of all names submitted for EMEA approval are rejected.
 - 83% rejections based on similarity with other existing products
 - 1.5% rejections based on names conveying misleading therapeutic connotations
 - 3.5% rejection based on names conveying a promotional message
 - 5.5% rejections based on name including INN stem or being similar with INN
- 60% of rejected names are accepted after justification.

Safety and Health Concerns

- Safety – avoid medication errors when prescribing, dispensing and administering of medicines
- Sound-/look-alike similarities **in print, speech or handwriting** with to:-
 - approved / marketed proprietary names
 - other Medicinal Products
 - commonly used medical terms, abbreviations, procedures and lab tests
 - INNS

Safety and Health Concerns

- Overlapping characteristics increase risk for name confusion
- Indications
- Patient population
- Formulations
- Strengths
- Shelf / storage space

Safety and Health Concerns

- Fanciful names, false or misleading claims
 - Superiority claims
 - Claims for different or expanded indications
 - Claims for efficacy or safety not supported by data

Managing Name Rejections

- No flexibility to adjust the name – eg, a minor variation in MS where there is confusion with an existing product
- Require risk management procedures put in place
 - have back-up names ready
 - reconsider global name
 - managing company expectations and communication to explain contradictory decisions from Regulatory authorities
- Manage name reassessment option – provide justifications if name is safe & supported by data
- Request the Commission for an exception?only if there is a trade mark legal conflict.

Requirements for justification

- All the NRG objections raised should be addressed
- Company to carefully review in which MS conflicting names are authorised
- Critical assessment of potential for harm to the patient in case of a mix-up (name safety testing)
- New information available to the applicant:
 - e.g: - Change of name (proof of acceptance)
 - Product withdrawn

Name Safety Testing

- What the name-testing agencies provide
 - Prescription interpretation studies of target healthcare professionals and pharmacists
 - Sound/Look Alike identification and analysis
 - Inappropriate or Exaggerative claim identification
 - Inappropriate INN stem identification
 - Linguistic, cultural and marketing evaluation

Example of Evaluating Overlapping Characteristics as part of Final Trademark Selection

TEST NAME	CLASSIFICATION	INDICATION(S)	DOSAGE FORM(S)	DOSAGE STRENGTH(S)	FREQUENCY OF ADMINISTRATION	USUAL DOSE	ROUTE	CLASS TYPE	STRENGTH TYPE
AVAXIL	Immediate-Release Opioid	Indicated for the treatment of acute pain	Oral capsules	200mg	2 times daily	400mg per day	Oral	Rx	Single

TEST NAME	CLASSIFICATION	INDICATION(S)	DOSAGE FORM(S)	DOSAGE STRENGTH(S)	FREQUENCY OF ADMINISTRATION	USUAL DOSE	ROUTE	CLASS TYPE	STRENGTH TYPE
AFAXIN	Vitamin a	Vitamin a deficiency	Oral capsules	Vitamin a palmitate 10,000iu (otc), 50,000iu (rx)	Once daily	Varies per condition	Oral	OTC	Multiple
APACIL	Aminosalicylate sodium	Tuberculosis	Oral syrup	Aminosalicylate sodium 2g, 4g	2-3 times daily	12gm/day	Oral	RX	Multiple

Name Safety Testing - So what is the problem?

- Methodology is not validated, therefore not always predictive
- Expensive to cover even major markets only; validity lost over time
- Impossible to cover all 25 member countries

Late rejection before launch

- FDA: tentatively accepted names are re-evaluated within 90 days of approval.
- NRG cannot identify names ahead in queue at NRG or at country (MRP, National) level which can lead to a rejection before approval.

Thank you

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