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Trademark Creation in a Global Pharma Environment

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1. Overview

- **Objectives**
- **Terminology**
- **Global trademark development**
- **Five major hurdles**
- **Facts and figures**
- **Conclusion**

2. Our objectives

- **Education**
- **Understanding**
- **Dialogue**

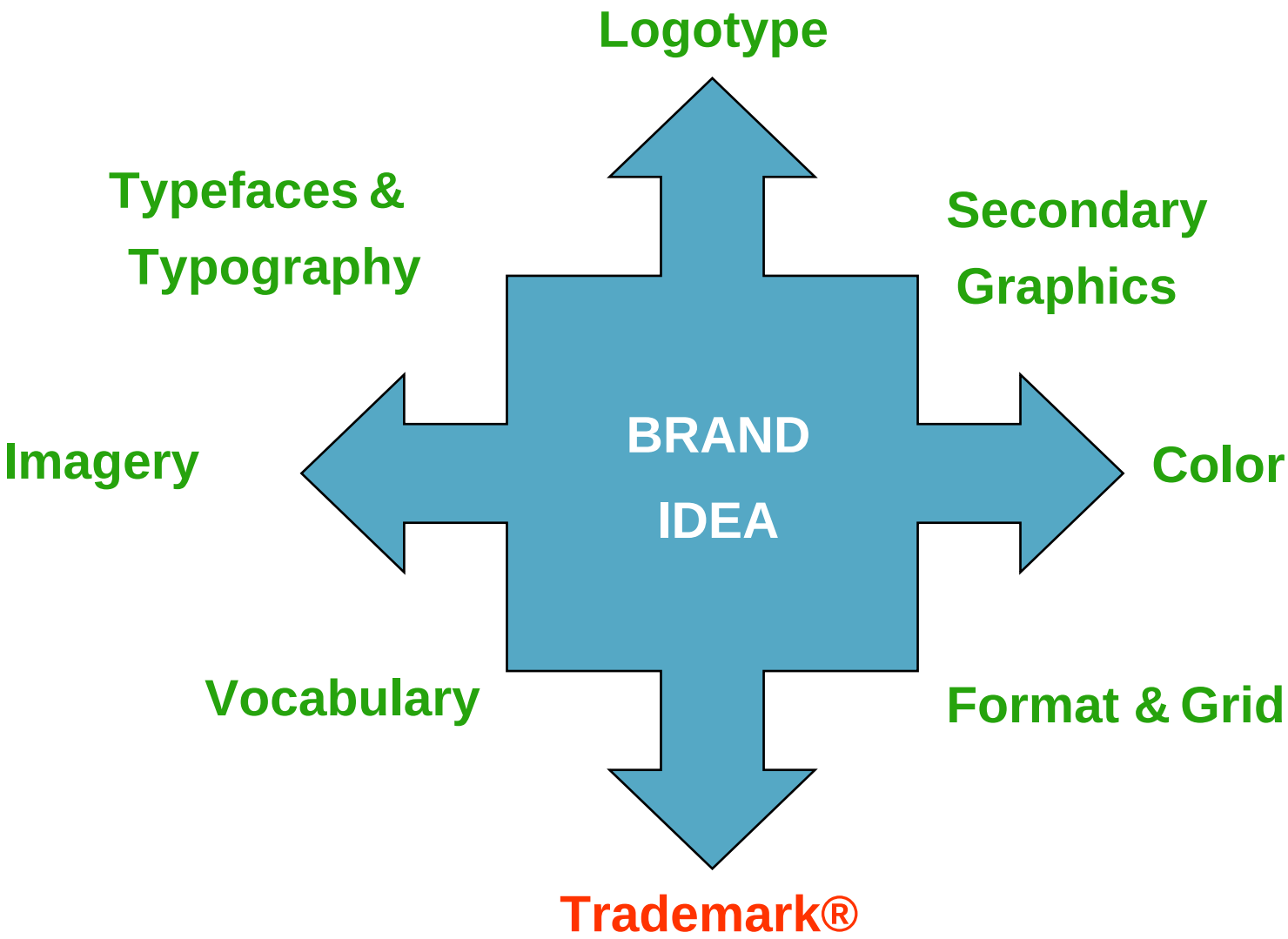
3. Terminology

- **Brand name**
- **Trademark**
- **Invented name**

3.1 What does a brand convey?

- **A brand is built through different elements:**
  e.g. communication, product performance, design, experience, etc.
- **It conveys a value to the customer by covering a need**
- **The aim of branding is to build customer loyalty**
- **In order to identify a brand, an exclusive brand identity is needed.**

3.2 Elements of Brand Identity



3.3 Function of a trademark

A TRADEMARK

- **Acts as an indication of origin and conveys to the public a guarantee of quality**
- **Distinguishes the goods/services of one trader from those of another**
- **Confers exclusive rights of use to the owner**
- **Confers defensive rights (copying/infringing)**
- **Can be renewed eternally (subject to requirements)**
- **Acquires goodwill over time**

3.4 Invented name

- **Article 1(20) Directive 2001/83/EC as amended**
  - **Invented name**
  - **Common name**
  - **Trademark**

4. Global Trademark Development

4.1 Objective of many pharmaceutical companies

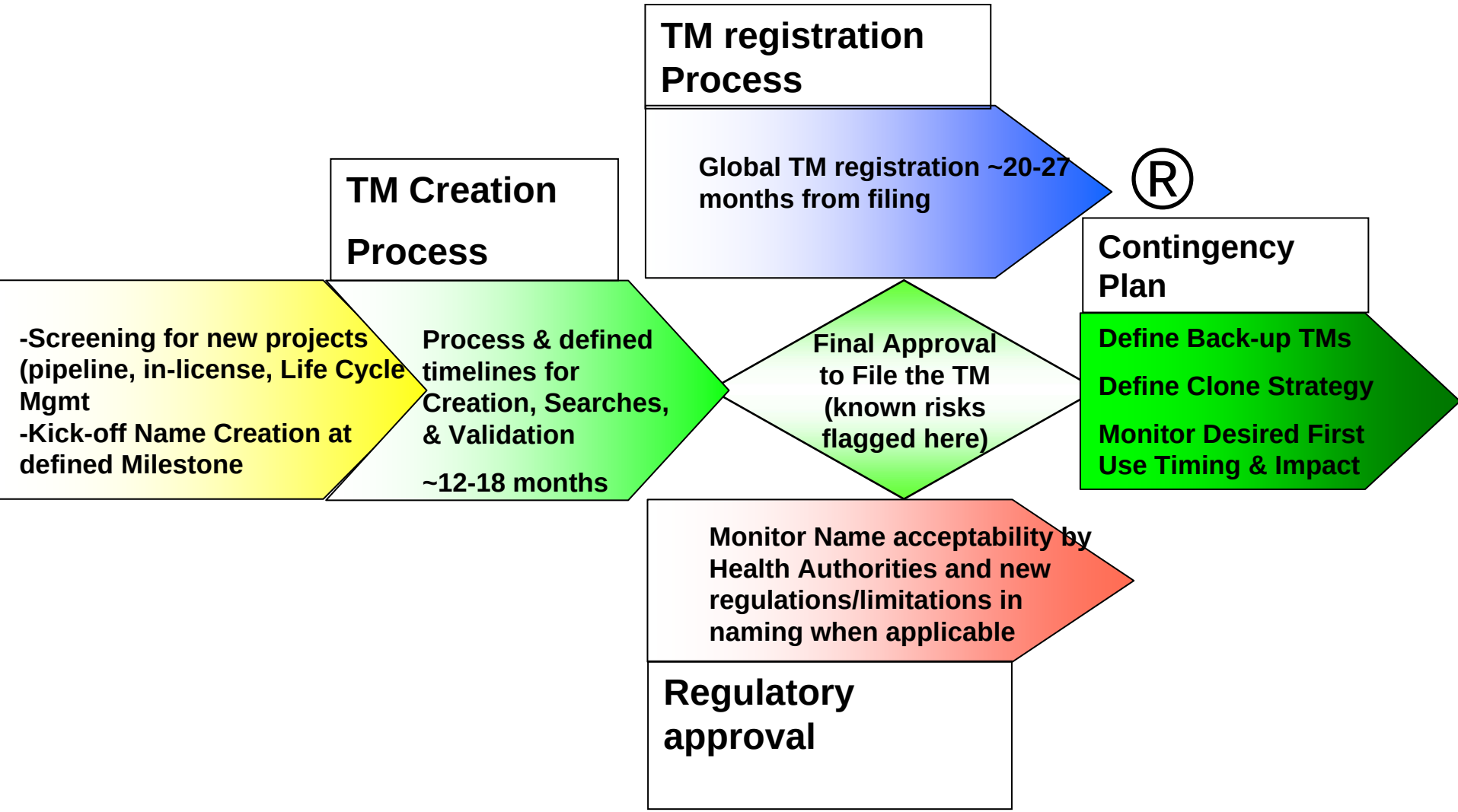
1. **Develop a global brand name**
2. **Why is this important?**

- **Reflects globalization of healthcare**
- **Brand recognition from all stakeholders**

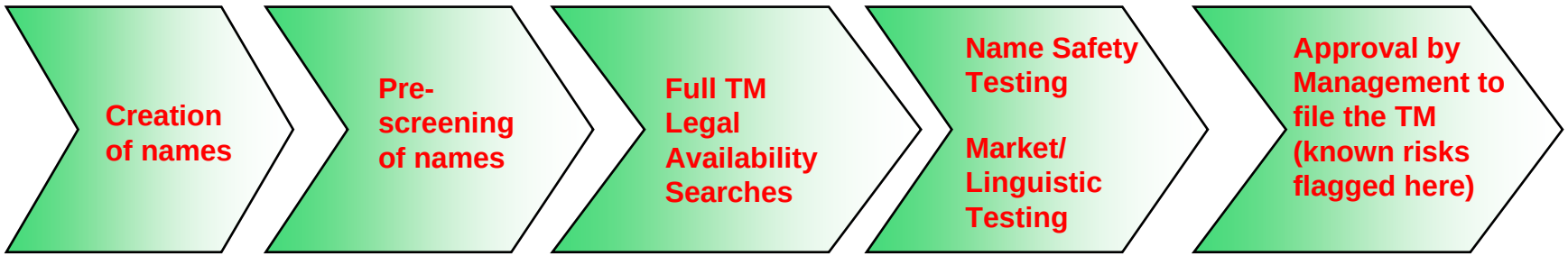
4.2 Facts and Figures I

- **TM creation mostly starts in Phase I or early 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**
- **500 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**

4.3 Global Process Overview



4.3 Trademark Creation Process



4.4 How can a company manage the process for optimal results?

- **Identify a multi-functional team**
- **Start the creation process early**
- **Anticipate set-backs**
- **Know the risks and plan accordingly**

4.5 How is Trademark Availability determined?

Objectives : **Determine trademark availability and identify trademark registration risks**

Criteria :

- **discard names for “absolute/relative grounds”**
- **Similarity evaluated according to major principle :**

  SIMILAR TRADEMARK + SIMILAR GOODS/SERVICES =

  INCREASED RISK OF CONFUSION
- **Check use situation of prior marks (current use or grace period)**

4.5 How is Trademark Availability determined?

Clearance process

Global search via cascade approach to minimize costs :

- **Initial Search through on-line resources including trademark databases, .com search and internet search**
- **In-depth Search through TM registers of US, EU and other major countries (CH,JP,CND,AR,AU,BR,MX,CN,TR)**

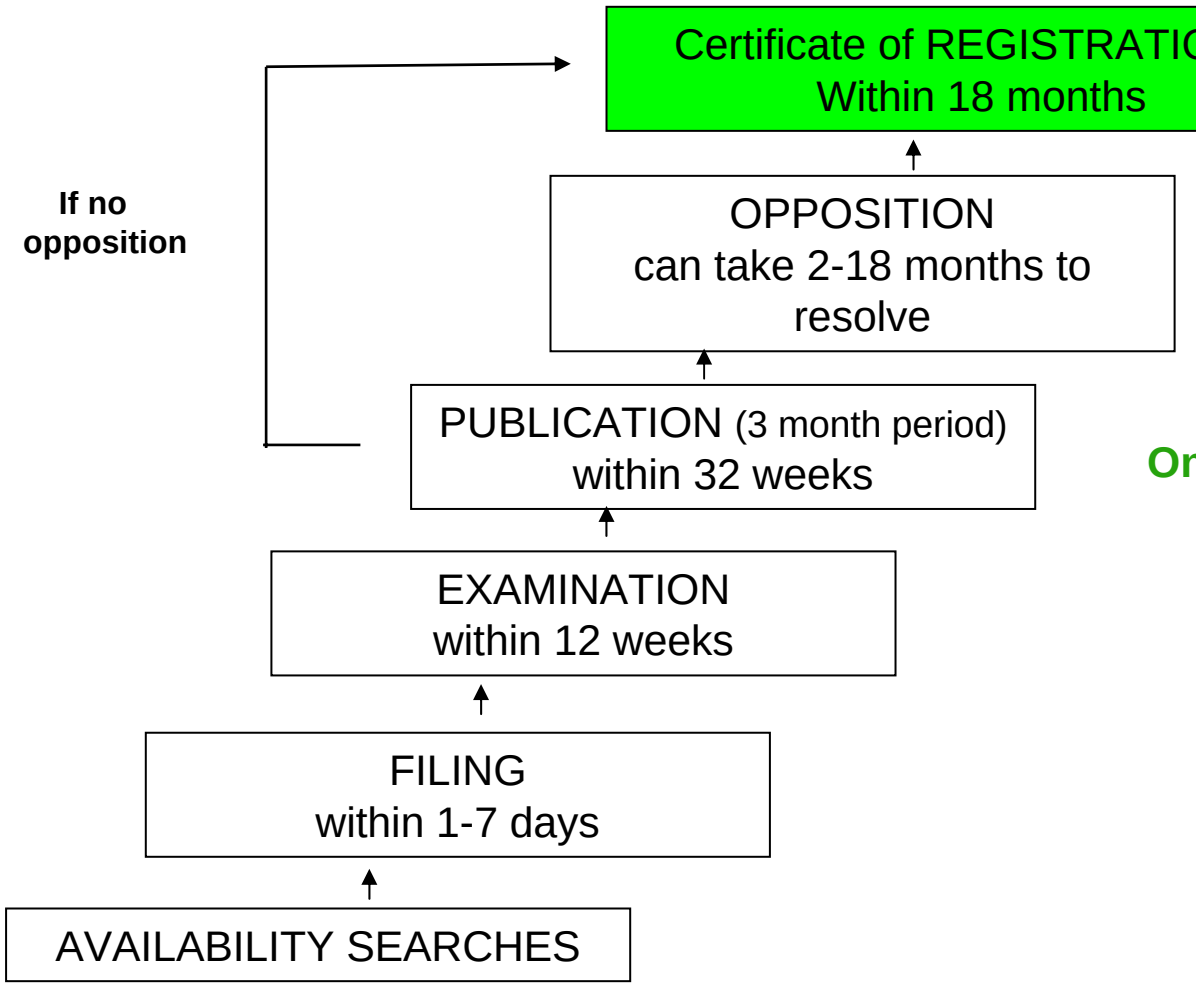
Consolidated report

Ratings: **LOW - no serious legal obstacles identified**

MEDIUM – trademarks may be subject to challenge but appear legally defensible

HIGH - unavailable due to serious legal obstacles

4.5 Average timeline from Filing to Registration for a Community Trademark



On average 8 to 36 months

4.6 Different systems for trademark registration

- **National trademarks - register trademarks separately in individual European countries.**

- **Community trademarks – a single registration providing trademark protection in the EU.**

- **International registrations - an international procedure to obtain multi-national trademark protection and international registration by way of a centralised system.**

Community trademark criteria

- **A Community trademark will only be allowed if no grounds for refusal exist in all the Member States.**
- **It is not possible to geographically limit a CTM to certain Member States.**
- **If a Community trademark is refused, it may be possible to convert to national rights in all the Member States where the objection did not arise.**
- **For the Member State(s) where the objection arises, it may be possible to register a variation or a new trademark as a national registration or a CTM.**

4.7 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**

4.7 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	N	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	US
APACIL	Aminosalicylate sodium	Tuberculosis	Oral syrup	Aminosalicylate sodium 2g, 4g	2-3 times daily	12gm/day	Oral	RX	Multiple	Italy

4.7 Principles of Regulatory Country Expert Review

- Some companies run internal name review before or concurrently with formal name testing (conducted by vendors)
- Purpose is to capitalize on vast internal knowledge in order to supplement formal testing
- Regulatory manager has overall responsibility for compiling input from the EU and other major markets
- Sample e-mails, assessment template and report template provided
- Regulatory manager consults local resources to check the names against locally authorised products
- Overall process timeline is 35 days

4.7 ABC123 Name Review Template

Name Candidate	Based on your current knowledge and awareness, does this name SOUND like an existing drug name, name for drug pending approval or drug in development? (pronunciation can vary).	Based on your current knowledge and awareness, does this name LOOK like another currently marketed product/drug in development or drug pending approval when printed or written?	In your opinion, does this name imply, imbed or suggest an inappropriate claim?	Based on your current knowledge and awareness, please list any other potential regulatory concerns regarding this name candidate.	Please provide your overall assessment of risk (low, medium, high) and rationale.
	Yes __ No __ Please list:	Yes __ No __ Please list:	Yes __ No __ Please list:		
	Yes __ No __ Please list:	Yes __ No __ Please list:	Yes __ No __ Please list:		
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4.8 A Centralised Function Maintains the Overview

Centralised function leads and manages the global trademark creation and development process

Provides Global Project Management incl. reporting and budget

Consultation for strategy, creation and testing of TM candidates

Co-ordinates Contingency Planning Activities

Enforces Trademarks against infringers and counterfeiters

Fully integrated into the Business

5. Five Major Hurdles

5. Five Major Hurdles For Developing Global Pharmaceutical Trademarks

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**
   - **25 countries, 19 languages, further increase in rejections expected**

5.1 Market Suitability

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!**

5.1 Marketing suitability – the Issue of Taste

5.2 Global Cultural/Linguistic suitability

Internal linguistic checks through global teams:

- **Common sense**

Reviewed by external linguists in approximately 100 languages

- **Check all relevant languages for:**
  - **Misleading meaning**
  - **Negative connotations**

5.2 Example of Linguistic Challenges

Trademark: ZORTRESS

- **Globally registered name; test well from name-safety perspective**
- **Linguistic Testing Reveals:**

ZORTRESS	SPAIN/PUERTO RICO/MEXICO	SPANISH	TRES	THREE

- **Raises concerns that the “Three” could be confused with mg strength or dosage regime, therefore name not selected to move forward**
- **Derivation in Spanish speaking countries could avoid the issue: ZORTROSS**

5.3 No. of TM registrations currently on the register for pharmaceutical products and medical devices.

It is more and more difficult to find distinct, globally available trademarks:

The picture changes every day

- **130,000 Trademarks in the US in Classes 5 and 10**
- **900,000 Trademarks in the EU in Classes 5 and 10**

For example on country registers:

- **170,183 active applications/registrations on the register in Spain**
- **121,135 active applications/registrations on the register in Germany**

5.4 Safety and Health Concerns

Safety – avoid medication errors

- **Sound-/look-alike similarities to:-**
  - **approved / marketed proprietary names**
  - **other Medicinal Products**
  - **commonly used medical terms, abbreviations, procedures and lab tests**
  - **INNS**

5.4 Safety and Health Concerns

Overlapping characteristics increase risk for name confusion

- **Indications**
- **Patient population**
- **Formulations**
- **Strengths**
- **Shelf / storage space**

5.4 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**

5.4 Safety & Health Concerns: How do we manage?

- **Names validated via simulated prescription interpretation study**
- **Local Regulatory experts evaluate names for potential conflicts**
- **Contingency plan:**
  - **Appeal if name is safe & supported by data**
  - **Global back-up trademarks and clones**

5.4 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**
- **Still cannot identify names ahead in queue at NRG or at country (MRP, National) level which can lead to a rejection**

5.5 Single Trademark Requirement in EU

Additional challenge:

- **Products approved via Centralised Procedure require one trademark that is acceptable to all Member States.**
- **Exceptions – Article 6 Regulation 726/04 incompatible with the Community Trade Mark regulations.**

What does this mean for the industry?

- More flexibility to obtain exceptions to the single trademark rule

- Guidance on regulatory concerns for sound/look-alike similarities

- Increased transparency on:

  (i) name evaluation from national competent authorities

  (ii) decisions by CHMP/NRG

6. Facts and Figures

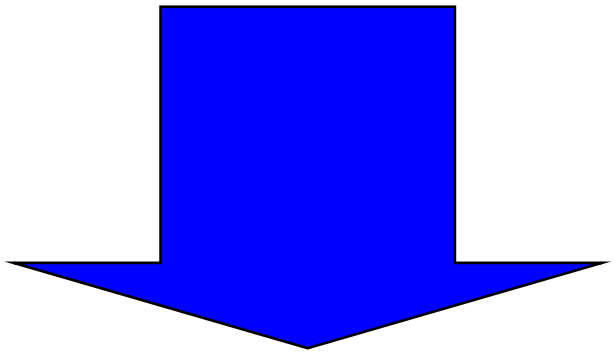
6. Facts and Figures II

Industry total in 2005:

- **EMEA received 41 new applications for medicinal products**
- **Approx. 20,500 names were created in order to have 1 main trademark and 2 backups for each of these new products**
- **Total cost for creation, searching, filing and health & safety testing of the trademarks amounts to approx. 20.5 Mio Euros.**

7. Conclusions

- **Start Early**
- **Flag risks at earliest stage**
- **Think “outside the box” for Creative Strategies**
- **Address the Issue of “taste” from the Start**
- **Make Health & Safety a TEAM Priority**
- **Always have a Back-up Plan**



Continued dialogue with EMEA