MED-ERRS
MEDICATION SAFETY
AWARENESS BROCHURE SET

EVALUATE-ERR®

What is EVALUATE-ERR?

Exclusive to Med-ERRS®, EVALUATE-ERR is a safety consulting service that examines a unique aspect of a product (such as a dosage form, special packaging, or trademark) and its vulnerability to user error.

Med-ERRS employs Failure Mode and Effects Analysis (FMEA) to determine which path or choice to follow to minimize the risk of error and provide specific recommendations and error-reduction strategies.

EVALUATE-ERR is also performed in response to specific FDA requests or as part of a risk assessment or a Risk Evaluation and Mitigation Strategy (REMS). In late 2012, the FDA released a draft guidance entitled, "Safety Considerations for Product Design to Minimize Medication Errors," which focuses on the utility of performing proactive risk-assessments in the early stages of pharmaceutical product design. Over the past several years, Med-ERRS has become more involved with providing this type of service in order to help develop risk mitigation strategies.

To view the full draft guidance, please visit:
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM331810.pdf

When should EVALUATE-ERR be used?

Pharmaceutical companies use EVALUATE-ERR to assist them with:

- Nomenclature strategy for a product line extension or new indication
- Non-proprietary name evaluation
- Determining appropriate packaging configuration
- Dosage expression (strength, form, schedule or formulation)
- End-user (practitioner or patient) instructions for use (IFU)

What may be included in EVALUATE-ERR?

Our EVALUATE-ERR service is uniquely tailored for each individual client and may consist of:

- Literature review and medication error analysis
- End-user feedback
- Failure Mode and Effects Analysis (FMEA)
- Potential error scenarios and assessment of harm
- Specific risk-mitigation strategies
- Summary of findings and recommendations

What is Failure Mode and Effects Analysis (FMEA)?

FMEA is a risk-assessment method based on the simultaneous analysis of failure modes, their consequences, and their associated risk factors.

Since the 1960s, FMEA has been used most exclusively in areas characterized by high risk, such as nuclear power plant operations, or by high cost, such as the weapons and aerospace industries.

In the pharmaceutical and healthcare industry, FMEA can be used to identify areas of potential failure when products are introduced into the complicated medication use system existing in our healthcare community today.

Med-ERRS®

ERR on the side of safety℠

info@med-errs.com 215.947.8306 www.med-errs.com

The Issue:
Family Tradenames

Over-the-Counter Brand Name Extensions: Family Tradenames

Over-the-counter (OTC) medication manufacturers can cause confusion when they extend the use of popular brand names within a line of products.

The same brand name has been used for products with opposing indications (for example, Kaopectate® products).

Many of these brand name extension products are packaged in the same type, size and color containers as the "original" product.

In some cases, pediatric patients are at risk for receiving medications that are not appropriate or safe for them (for example, there is a risk for Reye's Syndrome associated with children receiving aspirin and other salicylate-containing medications).

Without FDA review and specific approval of the OTC product names, companies have capitalized on well-known and trusted brand names and used them for other products, even if the product has different ingredients and uses.

Examples of Over-the-Counter Brand Name Extensions

Family Name	Trademark Extensions	Active Ingredients	Route	Form	Purpose	Manufacturer
ALLEGRA®	Allegra	Fexofenadine	Oral	Tablet	Reduce sneezing, running nose caused by allergies	Chattem
	Allegra Anti–Itch Cooling Relief Allegra Anti-Itch Intensive Relief	Diphenhydramine Allantoin	Topical	Cream	Topical analgesic, reduce itching	
CLARITIN®	Claritin Eye	Ketotifen fumarate	Intra-ocular	Eye drops	Nasal congestion, sinus pressure	MSD Consumer Care
	Claritin	Loratadine	Oral	Tablet	Allergic conjunctivitis	
TRIAMINIC®	Triaminic	Dextromethorphan Phenylephrine	Oral	Tablet, Capsule or Liquid	Cough suppressant, decongestant	Novartis
	Triaminic Fever Reducer	Acetaminophen	Oral	Syrup	Fever reducer, pain reliever	
KAOPECTATE®	Kaopectate Stool Softener	Docusate calcium	Oral	Softgel	Constipation	Chattem, Inc.
	Kaopectate Anti-Diarrheal Caplets Kaopectate Liquid (various strengths and flavors)	Bismuth subsalicylate	Oral	Caplet, Liquid	Diarrhea	
DULCOLAX®	Dulcolax Laxative	Bisacodyl	Oral, Rectal	Tablet, Suppository	Laxative (used as part of the preparation process for GI procedures)	Boehringer Ingelheim Consumer Products
	Dulcolax Stool Softener	Docusate sodium	Oral	Softgel	Constipation	

Awareness

Despite reports of confusion among various medications within several product lines of OTC medications, the pharmaceutical industry continues to extend the use of existing brand names. In doing so, these companies are posing the following risks:

- Patient Safety Risk: Avoidable adverse drug events arising from misleading naming practices where consumers are purchasing medications with active ingredients that differ from what they expect or what their healthcare practitioners have recommended for their condition(s)
- Trademark Risk: Potential association of a trademark with a misleading naming system

Prevention

Med-ERRS can provide consulting services for this type of issue using EVALUATE-ERR℠. This service offering can help develop appropriate tradenames across family brand names.

The Issue:
Same Trademark, Different Drug

The Issue

Pharmaceutical trademarks used in one country for a product may represent a different active ingredient in another country.

A United States patient taking DILACOR (diltiazem) had a prescription refilled while traveling in Serbia. DILACOR in Serbia is digoxin, and the patient experienced life-threatening cardiac problems. This information was initially published by the Institute for Safe Medication Practices: http://www.ismp.org/newsletters/acutecare/articles/20050127.asp

This issue is so widespread and potentially dangerous that the FDA issued a public health advisory on January 2006 describing 18 exact trademarks and 105 similar trademarks.

To view this list please visit:

http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/PublicHealthAdvisories/ucm173134.htm

Consumers who fill prescriptions abroad, either when traveling or when shopping at foreign internet pharmacies, need to take caution because foreign drugs may use identical or very similar brand names for products with different active ingredients.

Examples of same drug trademarks with different ingredients in the US and Europe

Trademark	Active Ingredient(s), purpose and manufacturer in US	Active Ingredient(s), purpose and manufacturer in Europe
DILACOR®	diltiazem angina, hypertension (Watson Laboratories)	digoxin (**Serbia**) congestive heart failure, arrhythmia (Zdravlje)
FLOMAX®	tamsulosin benign prostatic hyperplasia (Boehringer Ingelheim)	morniflumate (**Italy**) inflammation, pain, fever (Chiesi)
NORPRAMIN®	desipramine depression (Sanofi Aventis)	omeprazole (**Spain**) peptic ulcer, GERD (CEPA)
VIVELLE®	estradiol estrogen deficiency, menopausal disorders, osteoporosis (Novartis)	ethinyl estradiol, norgestimate (**Austria**) acne, tri-phasic, oral contraceptive (Janssen-Cilag)
SOMINEX®	diphenhydramine insomnia (Prestige Brands)	promethazine (**United Kingdom**) insomnia (Thornton & Ross)

Awareness

No international regulatory system exists to ensure that new trademarks are sufficiently different from those existing elsewhere in the world:

- Patient Safety Risk: Avoidable adverse drug events arising from overseas travel, drug importation and Internet prescription reporting
- Trademark Risk: Potential misuse of your trademarks and its good will in other countries

Prevention

Med-ERRS can provide trademark safety testing and screening that can help you avoid duplicate use of drug trademarks you are filing and managing.

About Med-ERRS®

Med-ERRS is an independent organization that works with pharmaceutical and healthcare industry professionals who specialize in trademark development, trademark law, regulatory affairs and drug safety. Our expertise is in evaluating trademarks for safety during the pre-market phase, for the purpose of reducing the risk of medication errors. We accomplish this by assessing the potential for look-alike and sound-alike confusability of trademark candidates with other drug products, medical terms and abbreviations encountered in the healthcare setting.

Med-ERRS®

ERR on the side of safety℠