Identifying and Preventing Medication Errors: An OTC Perspective

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Overview of OTC Drugs

• An essential, safe, effective, convenient and economical component of our healthcare system
• Must be safe and effective for consumer use without supervision of a physician
• Wide margin of safety accounts, in part, for low number of adverse events
• OTC label provides all the information consumer needs for safe and effective use
Potential for Medication Errors

• Dispensing Errors:
  – OTC medicines prepackaged at manufacturing plant

• Selection Errors:
  – OTC medicine label contains all the information consumer needs for:
    • Appropriate self-selection
    • Safe and effective use
  – More than 80% of consumers always read the label when making a first-purchase or use
Principal Display Panel
Adverse Event Reporting for OTC Medicines

• Monographed OTC Medicines
  – No requirement because they are generally recognized as safe and effective (GRAS/E)
  – Voluntarily submitted by companies

• NDA’d OTC medicines (Rx-to-OTC Switches)
  – Same requirements as prescription drugs

• Additional databases

• OTC labeling changed in response to adverse events
Consumer Education

- The New Over-the-Counter Medicine Label...
- Take a Look!
- OTC Remedies: *Cough & Cold, Stomach, Allergy, Headache*
- What's Right for You?
- Medicamentos sin receta: *Resfriado, Estornudo, Alergias, Dolor de Cabeza*
- ¿Cuál es adecuado para usted?
- Kid's Aren't Just Small Adults: Medicines, Children, and the Care Every Child Deserves
- My Medicines: Developed by the U.S. Food and Drug Administration, the Center for Drug Evaluation and Research, and Consumer Healthcare Products Association
- STOP...
- LOOK AGAIN!!
Recommendations

• Support CHPA’s efforts to require mandatory reporting of serious adverse events for OTC monographed medicines

• Continue to support and work with programs such as CHEC to educate consumers on:
  – Taking OTC medicines appropriately
  – Following the labeling
  – Informing about the risks of misuse
Conclusions

- OTC medicines are an essential, safe, effective, economical, and convenient component of our healthcare system
- Like all drugs, OTC medicines also have risks
- OTC medicines are safe and effective when used according to the labeling