
WORKSHOP: EFFECTIVE RX-TO-OTC SWITCHING

Switching around the world: United States

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Switching Around the World: USA

- Procedure, Timing, and Exclusivity Basics
- Recent Developments
- Collaborative Care?
- What Might Be Ahead?

Procedure, Timing, Exclusivity Basics

- NDAs/supp. NDAs today's route
 - Monograph switch possible, but none since 1991
- Note application is for the OTC product
 - i.e., labeling critical; no bifurcated registration/status decision
- Timing and Fees? Full NDAs - fee of \$256K. Efficacy supplements - \$128K. 1 year target, phasing down to 10 months by 2002 for NDAs; supp. NDAs with clinical data. (6 months phasing to 4 months for priority applications, resubmitted apps., supp. NDAs with no clinical data)

Procedure, Timing, Exclusivity Basics

- Keep definitions in mind: US Food, Drug & Cosmetic Act, as with EU Classification Directive, defines prescription medicines. OTC medicines are then the default status or starting premise

Procedure, Timing, Exclusivity Basics

- 3 year exclusivity extension where switch includes "new clinical studies" "essential" to approval of application
 - Not formally a patent extension, but similar impact
- 6 months exclusivity possible for pediatric studies
 - Requirements very detailed. Program sunsets beginning of 2002

Recent Developments

- ① Rx experience obviously typical and helpful, but *not mandatory*
 - Triclosan in toothpaste (Total® - 1997)
 - Bentoquatam for poison ivy protection (Ivy Block® - 1996)
 - New combinations, strengths, or indications without exact Rx equivalents
- ② Smoking cessation products *do* shift switch paradigm
 - Public health aspects in far sharper focus

What Might Be Ahead?

- Where does cholesterol fit?
- What about hypertension? Diabetes? Hormone replacement therapy?
- What are you seeking to prove to support a switch?
 - Stay tuned for CHPA's Dr. Bill Soller

Collaborative Care?

- Phraseology doesn't cross Atlantic, but concept is there, particularly looking toward new frontiers in switch
- Anticandidals remain the prototype
- Where does cholesterol fit?
 - Rx indication - yes
 - dietary supplement claims - yes
 - food claims - yes
 - OTCs indications/claims - no

