State Product Stewardship Initiatives: Industry Implications

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Pharmaceutical Life Cycle Management: The Perfect Storm

Growing environmental awareness

Increasing focus on environmental regulations

Efforts to “green” the manufacturing and supply processes

Calls for “Green Chemistry”

Public health issues: ODs and poisonings

Cost containment through waste reduction
What is Product Stewardship?

Shared responsibility for the end-of-life management for products which are deemed hazardous to human health or the environment.

Includes changes in product design and production, changes in consumer behavior, and decisions regarding cost of proper disposal.

Often involves competing agendas and differences of opinion as to what entity bears which costs and responsibilities.

Primary historical reference: Scott Cassel, Ex Dir, Product Stewardship Institute.
Historical Process

Government agencies/non-profits engage in discussions with manufacturers/retailers

Initial resistance of manufacturers to internalizing end-of-life costs into product price

Promotion of end-of-life fees

Slow movement towards the middle by both sides, resulting in greater responsibility taken by manufacturers and more flexibility by government
Learning from the Past

State legislative efforts are an important mechanism for moving issues forward nationally.

Gaining the acceptance and participation of the industry involved is a win-win for industry and the public.

Corporate leadership is vital for a successful program.
Extended Producer Responsibility Laws

Courtesy Product Stewardship Institute October 2009
What Has Worked(Relatively) Well: Battery Recycling

Portable Rechargeable Battery Association
Established Rechargeable Battery Recycling Corporation (RBRC) in 1995
Management of recovery and recycling of nickel-cadmium (NiCd) batteries
First national, industry-wide producer responsibility program in US
Ni-Cd batteries comprised less than 0.1% of MSW but accounted for 75% of cadmium content
Why Batteries?

RBRC prompted by 8 state laws with take-back requirements for rechargeable batteries
Growing interest in Europe to ban Cd
Passage of comprehensive legislation in MN and NJ
Battery industry sought federal legislation to facilitate
Mercury-Containing and Rechargeable Battery Management Act ("The Battery Act")
Made the Universal Waste Rule immediately effective in all states
What Could Be Done Better?

In spite of public education, many consumers unaware of program

Inherent in voluntary program are “free riders,” companies that do not support the program but benefit from the take-back efforts

Consider mandatory federal program with increasing performance goals to enable manufacturers to factor in costs as data is generated
Drug Take-back Pioneers: Charting Unknown Territory

How much consumer-generated drug waste occurs annually?
What percentage of drugs dispensed is wasted?
How much residual, historical waste is in the system that needs to be “flushed” out?
What is the most efficient method for collecting/processing drug waste?
How does efficiency correlate with convenience?
What will the costs of each system be?
Who should incur the costs?
What Makes Drug Collection So Problematic

Hundreds of manufacturers/repackagers
Consumer does not often have choice of products/brands
Difficult to separate by origin
  “Bring only those drugs manufactured by ABC drug manufacturer”
Controlled substance and other regulatory issues
Concerns regarding diversion/safety
Multiple distribution systems: retail pharmacy, mail-order, internet pharmacy, multi-national sources
Impact on Manufacturers

Have a stake in reducing drug waste if costs of disposal must be built in to cost structure
Potential reduction in sampling/move to vouchers
Encouragement of lower introductory prescription limits/options
Application of business process to increase efficiencies in take-back efforts
Economies of scale emerge
Reasons for Retailers & Manufacturers to Participate

Competitive Advantage: perceived as being “green” and leaders in sustainability efforts

Reduction of Business Risk: getting out in front of multiple state legislative efforts to support a mutually agreed upon federal effort

Company Leadership: Bold decision to lead
- Wal-Mart’s packaging scorecard initiative
- Home Depot’s Eco Options label program
- Whole Foods’ Whole Trade Guarantee
Reverse Distribution: Wholesale/Retail Success Story

Drug manufacturers have been “buying back” expired drugs for many years.

Development of reverse distribution industry in late 1980’s, early 1990’s accelerated and streamlined the process.

Reverse distributors initially reviled and mistrusted by some manufacturers.

Many manufacturers now embrace and out-source, resulting in cost reductions and economies of scale.

Greater visibility and ability to reduce outdate generation by pharmacies/wholesalers.
Current State Take-back Efforts

Communities across the country are exploring options for collecting and disposing unused medications from consumers.

[Map of the United States showing states participating in take-back efforts]

www.takebacknetwork.com
presented by
The Product Stewardship Institute
Proposed Product Stewardship Bills

Florida: HR 1357, SB 2650
Maine: HP0557, LD 821
Minnesota: HR 1217
Oregon: SB 598
Washington State: HR 1165, SB 5279 (duplicate)

None have passed to date – only a matter of time
Common Elements: General Consensus

Must accept all OTC, RX drugs; some include veterinary
Manufacturer or Importer; retailer not included
Target audience: consumers, including long term care facilities, other residential treatment centers, hospice
Plan Required of Manufacturer(s): Renewal times differ
Flexibility: Urban and rural/mail-back required in some; collection in cities of 10,000+ in others
Common Elements: General Consensus

Manufacturer(s) must cover all costs; administrative fee may also be levied by state; No fee allowed at time of collection

Must include either recovery goals first 3 years (lbs/capita) or other evaluation program

Must accept all unwanted covered products regardless of who produced them

Annual report (3 of 5 require)

Educational outreach required; toll-free number & website (3 of 5)
Common Elements: General Consensus

State Oversight: Varying degrees, with WA State the most highly defined
Pharmacy Responsibilities: Must publicize (3 of 5)
Performance Standards: Required (4 of 5)
Policies & Procedures/Track/Trace/Security: (3 of 5)
Stewardship Organization: To administer and track participation (2 of 5)
Common Elements: Lack of Consensus

Required Destruction Technologies:
Maine, Minnesota, Washington: Require Hazardous waste or superior technology

Florida, Oregon: Hazardous waste or other incineration
Finding a Way Forward

Determine cost efficiency for 3 scenarios:
   Community take-back
   Pharmacy kiosk
   Individual mailback

Define cost efficiency
   By individual? by family unit?
   By prescription? By pound?

Seek federal legislation which allocates funding
   based on agreed upon parameter

Sales into the market?
Volume into the market?
What’s Needed: Product Stewardship
Model Language

States are clearly adopting language from each other
Washington State, Maine, Minnesota very influential

Suggested Action Item:
  Draft model language that retains much of the acceptable common elements
  Involve industry in dialog
  Move the discussion to federal legislation with some state flexibility

Use federal act to move hazardous pharmaceuticals into Universal Waste Rule (UWR) in tandem with EPA
The Maine Declaration?

First mandatory 15-day introductory prescription for selected drugs as compared to 90 day automatic fill by mail-order pharmacies

“The Maine Declaration”
Support for limited first-time prescriptions on selected drugs based on returns data
No co-pay so consumer is not penalized
Track data – system may pay for itself
Discussion
References


Product Stewardship Institute
http://www.productstewardship.us/