
CONCLUDING PERSPECTIVES ON SELF-CARE IN HEALTH POLICY

Regulatory policy and self-care in the United States

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Agenda

Consumer expectations
Legal/regulatory framework
Approach to concept of "OTC-ness"
Tools: Data ➔ Information ➔ Communication
New Labeling Initiative
International Harmonization
Present Policy Challenges
Summary

Consumer Expectations

Access to self-care products
(convenience)
Access to good information
Access to products that are safe
Access to products that are good
value for money (effective
products)

Legal Perspective

1951

Durham-Humphrey Amendment to
Federal Food, Drug and Cosmetic Act

A drug is expected to be made available
without a prescription if, by following
the labeling, consumers can use it safely
and effectively without professional
guidance.

Two Avenues to OTC Market

OTC Monograph Process

No market protection
Easy access - no application
Good Manufacturing Practices (GMP)

New Drug Application Process

Market protection - patent/exclusivity
Full application or Switch supplement
Specific Manufacturing Requirements
Post-marketing Safety/Other Reporting
Obligations

Prescription or OTC?

Fundamentals

Can the condition be adequately self-diagnosed?

Can the condition be successfully self-treated?

Is the self-treatment product safe and effective for consumer use, under conditions of actual use?

Prescription or OTC?

POINTS TO CONSIDER

Need for physician evaluation of the condition?

Adverse effects of consumer mis-diagnosis or delay in correct diagnosis?

Effective Product use

Consumer understanding of product use

Consumer understanding of expected benefit

Consumer ability to assess treatment effect

Prescription or OTC?

POINTS TO CONSIDER

Safe product use

Consumer understanding of product directions for safe use

Consumer understanding of what to do if product isn't working

Consumer ability to identify adverse effects, and ability to determine when adverse events may require professional care

Tools

DATA ➔ INFORMATION ➔ COMMUNICATION

Label Comprehension Studies

Actual Use Studies

Focused Product Labeling

Education Campaigns

Additional Information Resources

On-going Safety Information

Communication Initiative

New OTC Labeling

Final Rule approved

Clarity - Plain Language, Readable

Consistent, predictable, simple format

Informative, focused

Consumer, Industry input

New Labeling Format

PROCESS TO DEVELOP

Readability Literature Review

Part 15 Hearing (Public)

Design and Graphics Consultants

Consumer Label Comprehension Studies (industry sponsored)

Industry Consortium Meetings

Public Feedback Meetings

Advisory Committee Meetings

Workshops under Drug Information Association Auspice

Required Headings

Headings

Drug Facts (title)

Active Ingredient

Purpose

Use(s)

Warnings

Directions

Other Information

Inactive Ingredients

Required Headings

Warning Subheadings

"Do not use" (absolute)

"Ask a doctor before use if you have"

"Ask a doctor or pharmacist before use if you are"

"When using this product"

"Stop use and ask a doctor if"

Pregnancy

Overdose warning

Simple

Amends General Monograph Warnings

Allows Interchangeable Terms
Simplifies Language

Permits Omissions
Eliminates Redundancy

Readable

Minimum type size
Readable fonts (i.e., sans serif)
Minimum leading
Graphical features
White space
Bullets
Dark print on light background

Goal

INDUSTRY AND REGULATORS

Promote Responsible Self-Medication

FDA: Provide independently vetted product information so truly informed consumer decisions can be made

International Harmonization

Harmony - not monotonal chant
Science - consensus easiest
Legal Systems: US only 2 categories
Liability
Distribution
Reimbursement
Parliamentary Oversight
Public Expectations of Government
Medical Practice/Medical Culture

Policy Issues

Cosmeceuticals
Botanicals
Dietary Supplements
Effects of final formulation changes: (topical products; extended release products)
On-going Safety Surveillance
Use of foreign marketing experience
Antimicrobial Resistance

Summary

OTC availability of products often has substantial value (ability to self-treat, increased convenience, lower costs)

Products appropriate for OTC marketing should/must be OTC

Some conditions/product not appropriate (risks of self-misdiagnosis/self-mis-treatment or risk of product's adverse effects - monitoring requirements)

Summary

Net overall public health effect for OTC use may be positive or neutral, but must not be negative

Information Communication and Comprehension are the keys

Proliferation of new categories of products present new challenges to industry, regulators, and most importantly - consumers

