Consumer Healthcare
Products Association

Comments of Consumer Healthcare Products Association
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Introduction

The Consumer Healthcare Products Association (CHPA), founded in 1881, is a national trade association representing manufacturers and distributors of over-the-counter (OTC), or nonprescription, medicines and nutritional supplements in the United States. Currently, CHPA members account for more than 90 percent of the domestic sales of OTC medicines. Furthermore, CHPA has been actively involved with FDA and other organizations in ensuring the safe use of OTC medicines and reducing medication errors.

An OTC drug must be safe and effective for consumer use without the supervision of a physician or other licensed prescriber, according to labeling that contains adequate directions for use and adequate warnings (21 USC 352 (f)). A prescription drug has a different safety profile. It is one that, because if its toxicity or other potential for harmful effect, or the method of use or collateral measures necessary for its use, is not safe for use except under the supervision of a physician or other licensed practitioner; or one that for reasons of protection of the public health is limited to use under the supervision of a licensed practioner under a new drug application (21 USC 353 (b)). While no medicine is completely safe, OTC medicines have a wide margin of safety which in part accounts for the low number of adverse events associated with their use. The OTC labeling is a critical element of an OTC medicine because the Drug Facts format provides all of the information a consumer needs for its safe and effective use.

OTC medicines are an essential, safe, effective, and convenient component in the nation's healthcare system. While OTC medicines are used broadly for the relief of aches, pains, allergies, heartburn, and skin irritation and itches, the expanding OTC options available today not only treat the symptoms of common ailments, but some can prevent disease like tooth decay; cure athlete's foot or vaginitis; and help manage recurrent conditions such as migraine,

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allergy, and the minor pain of arthritis. They also can help prevent a number of more serious illnesses and enhance the quality of life. For example, smoking and heart disease are among the leading causes of death in the United States. It has been estimated that smoking costs our nation almost $100 billion in excess medical and indirect costs from disability and lost earnings. Fortunately, there are safe and effective pharmacologic treatments available without a doctor's prescription to help smokers quit. OTC nicotine replacement therapies help Americans quit smoking, which saves lives and reduces healthcare costs. With respect to heart attacks, aspirin has been shown to be effective in preventing secondary myocardial infarctions and for long-term cardiovascular protection and physicians often recommend their patients take one low-dose aspirin on a daily basis.

By using OTC medicines, consumers save billions annually through fewer unnecessary doctors' visits, less time lost from work, and the relatively lower cost for OTC medicines compared to prescription drugs. OTC medicines are also available around-the-clock through more than 750,000 retail establishments, including more than 55,000 pharmacies across the United States. Of the approximately 3.5 billion health problems treated annually, two billion (57%) are treated with an OTC medicine (American Pharmaceutical Association, 1996). Seventy-three percent of Americans would rather treat themselves at home than see a doctor, and six in 10 say they would like to do more of this in the future (Roper Starch Worldwide, 2001). Not only do OTC medicines save consumers money, but the economy and healthcare system also benefits through reduced lost worker productivity and fewer unnecessary physician visits (Lipsky, 2004).

Regulation of OTC Medicines

All OTC medicines are approved by the FDA either by virtue of being included in the OTC Drug Review Monographs or being approved through the New Drug Application (NDA) process. OTC Drug Monographs provide a list of active ingredients that have been reviewed by panels of experts (OTC Drug Advisory Panels) and are "generally recognized as safe and effective" (GRAS/E) by FDA. There are currently 44 OTC drug monographs that cover a broad range of OTC categories, including antifungals, anticaries, antiperspirants, antacids, laxatives, and many others.

Since the mid-1970s, FDA has switched more than 80 ingredients, dosages, or indications from prescription to OTC status. Many of these switches have occurred through the NDA process in which information about safety and efficacy in the proposed OTC population has been submitted to FDA for review. Many of these switches were first-inclass switches and underwent an additional review by a group of experts (the Nonprescription Drugs Advisory Committee) prior to FDA approval. Many of these switches have been for lower doses, different indications, and for shorter periods of usage compared to their prescription parents. This provides an added level of safety for these OTC medicines. In addition to establishing safety and efficacy, many recent Rx-to-OTC switches have entailed extensive label comprehension and actual use testing. In label comprehension studies, a diverse population of consumers is asked a number of questions about the product label to determine if the label clearly communicates the uses, directions, and warnings, and enables consumers to make judgments about whether this is a product that is appropriate for them to use (self-selection). In actual use testing, consumers are allowed to use the product in as close to an OTC setting

as possible (no direct medical supervision), where appropriate self-selection, compliance with the product label, and safety during actual consumer use are measured. These two types of studies are used to predict consumer behavior once the OTC drug is approved and marketed to the general population. Additionally, an OTC medicine approved via the NDA process also has been marketed for a substantial number of years as a prescription drug, which means that the safety profile of a drug is well characterized before the switch to OTC status. In summary, for a drug to be switched from prescription to OTC drug status, the drug must be safe and effective, consumers must be able to use the drug safely according to the labeling and without physician supervision, and the benefits of OTC use must outweigh the risk.

Handling of Adverse Events for OTC Medicines

For drugs that are marketed under the OTC Monographs, there is no requirement to report adverse events to FDA. This is because the active ingredients of these products are considered generally recognized as safe and effective (GRAS/E) and meet the labeling standards in the particular monograph. Many companies do voluntarily report serious adverse events to FDA under MedWatch. Serious adverse events are defined by FDA as death, a life-threatening event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect (21 CFR 310.305 (b)). In 1992 CHPA petitioned FDA to make mandatory the reporting of all serious and unexpected adverse events for monographed OTC medicines. In addition to the FDA MedWatch program, information about adverse events for OTC medicines is captured by other databases such as the Toxic Exposure Surveillance System (TESS) of the American Association of Poison Control Centers (AAPCC) and the government Drug Abuse Warning Network (DAWN). All of these databases are used to assess the safety of OTC medicines.

All OTC drugs approved by the NDA process are subject to the same adverse event reporting regulations as prescription drugs. OTC NDA'd drugs are required to report, within 15 days, any serious adverse events, and to provide periodic safety update reports to the FDA on all reported adverse event, regardless of the severity or medical outcome. In addition, companies are required to file an annual report of adverse event reports.

Many OTC product labels contain a 1-800 toll-free telephone number for consumers to contact the company for more information about the product and to report adverse events. Consumer inquires are answered by call centers that are staffed by healthcare professionals and/or trained technical staff. Of the calls companies receive on the 1-800 telephone lines, the vast majority have no relation to adverse events or safety. They relate to questions about product availability, product sizes, and cents-off coupons. Of the calls that pertain to adverse events, the vast majority are for nonserious, transient side effects that resolve quickly. In 2003, three major OTC companies received approximately 1 million consumer calls via their 1-800 numbers. Of those calls, 80,000 were about adverse events and, importantly, fewer than 600 were reports for serious adverse events associated with the OTC medications. For nonserious adverse event reports, companies obtain a minimum data set about the adverse event and no active follow-up is initiated. These nonserious reports are entered into a specific company database and used for trend analysis on a periodic basis. If a consumer reports an adverse event that is serious, or potentially serious, permission to contact the consumer's healthcare professional is requested. Some companies conduct an active query or dialogue

with the healthcare professional that is focused on obtaining as much information as possible from the consumer on the adverse event, with a detailed history taken. Serious adverse events are reviewed as to whether a change to the product labeling is warranted.

As mentioned above, consumer calls are periodically evaluated to determine if the labeling can be improved to communicate with consumers. One example is improved labeling for a petroleum-based cough/cold rub in which the company observed, from a few consumer calls, that some consumers were heating the product in water in a microwave. The use of microwaves was unrecognized at the time of the OTC Drug Advisory Panel review. Based on the adverse event reports, company proactively added additional warnings not to microwave the product or "add to hot water or any container where heating water," as this "may cause splattering and result in burns," and advised FDA that this language should be included in the OTC monograph. In another case, a company received spontaneous reports of a specific population of consumers intentionally taking more then the recommended dose of a product for the treatment of upper respiratory infections. In this case, a caution statement was added that intentionally exceeding the recommended dose may result in unintended health effects.

With respect to overuse and misuse, all OTC medicines bear labeling that instructs parents to keep the product out the reach of children and, in case of overdose, to "get medical help or contact a Poison Control Center right away."

Drug Facts Labeling

There are significant differences between the labeling of prescription drugs and OTC medicines. Prescription drugs are available only upon the written or verbal order of a physician or other licensed prescriber. While written information may be available through MedGuides or voluntary initiatives, containers bear little written information and the packaging is subject to dispensing errors. Even with the MedGuides, a lot of the information is not designed or tested for consumer understanding.

In contrast, the OTC medicine label contains all of the information the consumer needs for safe and effective use. OTC drugs are prepackaged by the manufacturer. Therefore, there is little, if any, concern that consumers will be getting the wrong medicine in the container, as the medicine is virtually untouched between the manufacturer and when the consumer opens the bottle. OTC medicines are manufactured, as are prescription drugs, under strict regulations set forth by FDA (Good Manufacturing Practices) and manufacturing plants are inspected by FDA to assure the quality of OTC products.

The OTC medicine labels contain necessary information that is pervasively regulated by FDA. OTC labels include information necessary for safe and effective use of the product and for consumers to make the decision, at the point of purchase, if this is the right product for their symptoms/disease. The Drug Facts label on the back and sides of the OTC container provides this information in a standardized format. In this way, the OTC label further reduces the chances of medication errors.

When purchasing an OTC medicine, the first thing a consumer sees on the store shelf is the product's principal display panel. This contains the brand name of the product and other important information to help consumers identify if this is an appropriate product for the

condition they want to treat. The label contains the name of the active ingredient and, perhaps, a statement about the product's benefits such as "relieves or treats" some type of ailment. It also contains the statement of identity which includes the general pharmacological category (e.g., "analgesic"). The statement of identity is written in layman's language and must be prominent and conspicuous. And, for those products with combinations of ingredients, there must be a statement about the principal intended action of the mixture. This is a requirement on all OTC products. All of this information is clearly visible to the consumer at the point of purchase and helps the consumer decide whether the product is right for them.

The next thing a consumer sees when choosing a product is the Drug Facts labeling. The Drug Facts label regulation standardizes all of the labeling information on the back and sides of the package to make it easier for the consumer to read and follow. The information is very clear, concise, and is organized in exactly the same way on every OTC product. This facilitates consumers finding all of the important information they need and to easily compare active ingredients and other information on products.

Drug Facts organizes the information in a way that is logical and helpful to consumers. It begins with:

- Active ingredient(s) in the product, including the quantity of each active ingredient per unit dosage
- Purpose of the active ingredient(s)
- What the product is used for
- Any warnings about use of the product, grouped by headers to facilitate the consumer finding and understanding the information. Note that the "do not use" statements appears before statements such as "ask a doctor or pharmacist . . ." In other words, absolute contraindications precede conditional statements or in-use precautions. Often the risk or consequence of the warning is explained.
- Directions for use
- Other information, such as storage conditions, etc.
- A list of the inactive ingredients in the products, in alphabetical order, so the consumer can know what is in the product in case they may have an allergy to one of the ingredients
- Where to seek information if a consumer has questions or comments such as the listing of a 1-800 number.

Specific patient populations are also taken into account in the OTC labeling. Specific dosing instruction may be provided for use in children, or the label may instruct the consumer to consult a physician for use in a specific age group. Specific warning statements are included for certain subpopulations who may have an co-existing condition (e.g., people with asthma, ulcers etc.), who are taking another medication that may interact with the OTC medicine (i.e., drug-drug interactions), or who should not use the product, or in which the product may cause a serious adverse event (e.g., Reye's Syndrome warnings on aspirin-containing products for children and allergy alerts on several OTC medicines).

The above elements must be displayed in a "Drug Facts" box with the heading "Drug Facts." The rule specifies the minimum type size and use of a specific type. It also prescribes the use

of barlines and hairlines of specific thickness, use of bullet points for clarity of the information, and use of upper and lower case letters.

FDA said that it designed the Drug Facts rule to ensure that all material facts about the safe and effective use of OTC drug products are adequately presented to the consumer with such conspicuousness and prominence that they are likely to be read by the ordinary individual under customary conditions of use. The agency explained that the standardized format, in conjunction with content requirements, should help the consumer to readily and meaningfully compare OTC drug products, and minimize the potential for consumer confusion when comparing products with the same pharmacological class (62 Fed. Reg. at 9043 (February 27, 1997)).

A recent survey of a nationally representative sample of 1,002 adults aged 18 or older in the United States showed that 81% of consumers always read the label when making a first-time purchase of an OTC medicine and 79% always check it when using one of these products for the first time (Prevention Magazine's National Survey of Consumer Use of Over-the-Counter Medications and Dietary Supplements, 2002).

OTC Medicine Advertising

While both prescription and OTC drugs are advertised directly to consumers, there are several important differences. Prescription drug advertising is regulated by FDA, whereas advertising for OTC medicine is regulated by the Federal Trade Commission (FTC). Another difference is that direct-to-consumer prescription drug advertising must provide information about warnings. OTC drug advertising does not have this requirement because all of the warnings and other information consumers need to decide if this is an appropriate product for them to purchase, and instructions on how to use the product are provided on the package at the point of sale. Over the course of several years in the 1980's, the FTC considered, and specifically rejected, requiring warnings in OTC advertising.

There are several oversight structures that review OTC medicine advertising. The first review process is in within the OTC manufacturing companies in which multifunctional teams of marketing, legal, research and development, regulatory personnel and many others review the advertising claims and the support. They focus on making certain that the advertising is consistent with the product label and the underlying science supports the product claims. Next, all of the major television and many cable networks have Broadcast Standards Departments containing legal, medical, and scientific personnel to review the advertising against their internal standards and ensure the product claims are true and not misleading. In specific cases, the National Advertising Division (NAD) of the Council of Better Business Bureaus, a non-governmental organization funded by the advertising associations, focuses on, not just the words in the advertisement, but also the net impression being conveyed to the consumer. The NAD also evaluates if there is adequate support for any product claims and, importantly, if there is a good fit between what the product does and the message being conveyed. It has a phenomenal record of 96% voluntary compliance with its decisions. Companies who decline to abide by the NAD process are referred to the FTC which gives those cases top priority.

All OTC medicine advertising is subject to oversight by FTC, a government agency that monitors and acts on deceptive or unfair practices. All advertising must be truthful and not misleading. It must have adequate substantiation to support both objective claims and implied claims. FTC works closely with FDA when it comes to OTC medicine advertising, relying heavily on FDA scientific expertise in evaluating the truthfulness of claims and compliance with the OTC Monographs and NDA approvals.

Industry Activities on Patient Education and Compliance

Over the past decades CHPA has developed and disseminated a wide range of educational materials to enhance consumer education about the appropriate use of OTC medicines and to increase consumer compliance. Just last year, CHPA and FDA produced the first-ever bilingual edition of *Over-the-Counter Medicines: What's Right for You?* CHPA and FDA also published *Kids Aren't Just Small Adults*, in English and Spanish, which provides information to parents about giving the right medicine in the right amount to children, knowing the active ingredients in children's OTC medicines, and discussing the difference between a tablespoon and a teaspoon. *My Medicines*, another consumer education pamphlet of CHPA and FDA, provides a question guide for consumers to discuss their medication with their doctor and a chart to record all of their medications, including prescription drugs, OTC medicines, and dietary supplements. CHPA also continues to distribute the booklet entitled *The NEW Over-the-Counter Medicine Label . . . Take a LOOK*. This booklet describes how to read the OTC Drug Facts label and provides important information about tamper-evident packaging and reinforces that consumers should always "read the label."

The *Back-to-School Kit for Parents* was published with the National Women's Health Resource Center and *A Parents Guide to . . . Preventing Teen Cough Medicine Abuse* was published with the Partnership for a Drug-Free America (PDFA). The kit and brochure both focus squarely on the issue of OTC cough medicine abuse. Both publications provide parents and caregivers important information about the possibility of teenagers abusing dextromethorphan-containing cough medicines, and are part of CHPA's overall efforts to focus awareness of the issue among parents, educators, law enforcement, and healthcare professionals.

CHPA and its members long supported the Council on Family Health (CFH), founded in 1966, an educational foundation devoted to public education on OTC medicines. In 2004, CHPA significantly built on the CFH heritage, creating a new educational foundation. The Consumer Health Education Center or CHEC has a mission of improving the health and well-being of consumers through appropriate, safe and effective OTC medicine use. CHEC provides leadership and conducts educational and research activities that foster the coordination of industry, government, academia, media, and other sectors. The foundation develops and implements consumer programs that will impact the safe and effective everyday use of OTC medicines and thereby lead to healthier consumers. This foundation is funded by CHPA member companies. The first year was focused on understanding attitudes and behaviors of consumers taking OTC medicines and a program is being developed to reinforce the appropriate use of OTC medicines and increase consumers' awareness that OTC medicines are real medicines with potential side effects.

Challenges Facing Industry

We know that consumers do read the label for OTC medicines, but we also know that they do not always strictly follow them. Research conducted by such prestigious groups as Roper Starch (2001), Prevention Magazine (2002), as well as CHEC continues to provide some insights into consumer behavior when using OTC medicines. For example, consumers may not be scrupulous enough about re-reading the OTC label thoroughly, following its directions, and heeding its warnings. Understanding these insights will help CHEC develop a series of well-targeted messages that will move us significantly towards the goal of better OTC label compliance and understanding that, with any medication, there are risks.

Recommendations

CHPA recommends the Committee on Identifying and Preventing Medication Errors:

1. Support CHPA's efforts to require mandatory reporting of serious adverse events for OTC monograph medicines and dietary supplements.
2. Continue supporting and working with programs such as CHEC to educate consumers on taking OTC medicines appropriately and on following the labeling, and to inform them about the risks of misuse.

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