OPINIONS

More on the New DTC Guidelines

PharmaVOICE received an overwhelming number of responses to our January opinion question, which addressed the FDA proposed changes to the regulations that govern the content and format of the product disclaimer or brief summary that must accompany print advertising of DTC products. PharmaVOICE thanks all of you who took the time to respond and welcomes the opportunity to keep the discussion open for another month.

An accurate portrayal

I'm in favor of the new guidelines. If the info really is revamped, this change on ads is likely to give a more accurate portrayal of the risk and severity of side effects. Consumers will be more likely to raise questions with healthcare practitioners if they are not frightened by the ad.

Tamara Schiller
ACCOUNT DIRECTOR
THOMSON PHYSICIANS WORLD

A prototype for the future

The Quantum Group was asked to prepare prototypical ads that envisioned what the print draft guidance could look like in practice. This exercise was highly enlightening, as it demonstrated a number of factors to be considered:

1. The differences in size, severity, and complexity of the risk information across categories make it difficult to create one overarching set of guidelines.

2. The longer fair balance categories (i.e., diabetes, contraception) render it virtually impossible to condense the information into the proposed box.

3. There is the potential for redundancies in the information, which is counter to the idea of simplifying the presentation of the risk information.

My assessment is that while the objective of the guidance is exactly what the data suggest should be done, with the exception of a more widespread use of patient-friendly P.I.s, I don't see DTC print advertising looking significantly different for the vast majority of brands pursuing this avenue. The allergy category, in particular, could be one exception to this projected status quo, but I don't think there will be many others.

The other major issue raised in the new guidances, the desire for increased use of unindicated/disease state advertising, also is a sound recommendation. Crafted in the right manner, unindicated advertising can help both large and small share brands and should be explored more widely by our industry.

Stuart Klein
PRESIDENT
THE QUANTUM GROUP,
A COMMONHEALTH COMPANY

A welcome benefit

There is no question that the current P.I. is both long and intimidating. Simpflying the brief summary accompanying print ads would be a welcome benefit to consumers, so long as the FDA sets consistent guidelines for what goes into the simplified version. Obviously, it would cover the basics. But the FDA also needs to provide specific quantifiable requirements for information, such as any side effects that occurred in more than 5% of patients. This would ensure consistency and patient safety along with consumer friendliness.

Unbranded TV spots that expand disease awareness, however, would benefit companies whose drugs are already market leaders in large therapeutic categories. These companies — whose products are already top of mind — can capitalize on spots that broaden the market. But companies whose products are not market leaders will incur a huge financial burden with no benefit or return from their investment. While this may have educational value, I would recommend that such spots be voluntary rather than required.

Rich Levy
PRESIDENT
HEALTHSTAR ADVERTISING

Enhancing patient care

As a practicing physician, I have seen a direct correlation between patient awareness and the rise of DTC in print, broadcast, and on the Web. This awareness, from my perspective, has enhanced patient care through earlier diagnosis and better compliance. It's also been a major factor in the remarkable growth of Internet health sites.

Because brief summaries are so intimidating, patients often overlook them, even though they bring ads to their physicians about products they see in magazines and on TV — and then ask for information that's printed in the P.I.

So I'm all in favor of simplifying the brief summary to enable consumers to better understand medications they read about or see on TV.

Ash Nashed, M.D.
CEO
CHOICE MEDIA

What's Your Opinion?

OFFSHORING — A LIFE-SCIENCES DEBATE

Because of pressures to cut costs, life-sciences companies are outsourcing more and more of their services to offshore locations.

In this month's Outlet, Publisher Marcy Holeton cites that the practice of offshoring is commonplace in such disciplines as information technology — coding, programming, remote management, operations; finance — transaction processing, administration, and contact roles; and call centers throughout many industries. Deloitte & Touche has predicted that $356 billion in operating expenses in the global financial services industry alone will be relocated off shore within the next five years.

As the debate among life-sciences executives heats up, PharmaVOICE wants to know your opinion on the merits of outsourcing services and processes beyond U.S. borders.

WHAT'S YOUR OPINION?
Please e-mail your comments to feedback@pharmavoice.com.