December's Regulatory Focus: APL and the role of social media

By Moulakshi Roychowdhury, PharmD, JD

December 2020. It's been just one year since we finished the last Regulatory Focus issue on advertising and labeling, yet it feels like a lifetime. In March, as the true impact of COVID-19 kicked in and we retreated from the office space to our home offices, it was hard to envision how we would prevail, both personally and professionally. But our industry, and particularly regulatory advertising and labeling, did not skip a beat and instead, stayed the course and persevered in its mission to protect public health. Many in our community lost loved ones or became caretakers overnight, while some had to address their own illnesses or take on multiple home-based roles as teachers while juggling work obligations. Others experienced mergers and acquisitions, downsizing (particularly terrifying during a global pandemic), and integrations, and to top it all, the US was navigating a hotly contested presidential election. The challenges were relentless, yet through it all, we have found and strengthened our humanity and empathy and become more resolute to be agile and creative in addressing the challenges so that patients can have continued, safe access to their medications.

As my issue co-lead Linda Pollitz and I started brainstorming ideas for the issue and reviewing the submitted articles, a clear theme quickly emerged.

The COVID-19–related safety measures restricting in-person promotional activities, such as office-visits, commercial shoots, and speaker programs, were forcing the authors to rethink how they could operate in this new world order. It became paramount for pharmaceutical companies to be agile and flexible so that they could continue disseminating truthful and non-misleading, balanced information quickly, efficiently – and digitally – to patients and healthcare providers.

Ways to connect

Agility and creativity are also the key drivers when it comes to communicating and maintaining continuity as we work remotely. Regulatory professionals and the pharmaceutical industry have rapidly adapted to tele- and video-conferencing to stay connected and keep projects on track. They have proved they can be just as effective, and perhaps more so, when working remotely. In *Building Bridges Through Communication: Lessons Learned in 2020*, **Luke Catanzaro** provides some helpful tips on video conferencing, phone calls, active listening, and trending business applications as a way of sharpening communication skills and improving business and regulatory interactions. But he cautions that tele- and videoconferencing are not one-way interactions – participants need to be active contributors to discussions as well as active listeners.

With digital and virtual communications now so integral the success of businesses, regulatory professionals need to keep an open-mind and strategize carefully in applying existing rules to new forms of media, particularly social media and podcasts. In *Leveraging the Power of Digital/Social Media Platforms to Compliantly Meet Business Objectives*, **Stephanie Jamieson** and colleagues discuss considerations for compliantly leveraging digital and social media platforms to meet pharmaceutical business objectives in the US. The authors outline the approach of Otsuka America Pharmaceutical Inc in developing processes, reviewing and approving digital/social media content, and using electronic Form FDA 2253 submissions of related promotional materials. They assert that, when social media is leveraged in the right way, it can further our mission in protecting public health and improving the lives of patients.

The pandemic has taught us how to harness the power of social media. As regulatory professionals, we must ensure we fully understand social media and are ready to champion it for the purpose of protecting public health. Along those lines, **James Jeng** evaluates how best to apply existing regulations to podcasts. In *OPDP compliance and promotional considerations for podcasts and audio-streaming*, he discusses using podcasts and audio-streaming platforms for promotional and nonpromotional activities and how that relates to the pharmaceutical industry. He provides a rudimentary overview of the current landscape, then outlines promotional considerations from a regulatory perspective to maintain compliance with the Office of Prescription Drug Promotion (OPDP).

Regulatory professionals in the pharmaceutical industry did not miss a beat through the pandemic, and neither did OPDP. Before COVID-19, the office issued one warning letter in February 2020. Since then, it has issued five more to date, three of which were warning letters. One warning letter in particular was for a prescription drug inappropriately promoted as a treatment for COVID-19. **Kim Do** provides an in-depth assessment of this letter and OPDP's role in these uncertain times. In *Deep Dive Into OPDP's Position on Public Health Emergencies in the US*, Do explores OPDP's views on public health emergencies, including COVID-19, and how they affect drug promotion. She reviews trends in past enforcement letters and concludes that promotional materials relating to current public health emergencies are heavily scrutinized by OPDP, something regulatory advertising and promotion reviewers should bear in mind.

Going digital

With different ways of working, such as alternative means of engagements with HCPs and patients and new digital opportunities, the ability to promote drugs has expanded considerably. That growth requires the pharmaceutical industry to adapt. In *Optimizing metadata fields for promotional material review in the US*, **Kishan Mistry** notes that optimizing such fields by implementing various levels of customization and configuration can help individualize the review systems used for promotional material review. These changes could strengthen processes to conduct cross-functional, risk-based decision making in a compliant manner and ensure pharmaceutical companies are aligned with their proposed messaging of promotional materials intended for healthcare professionals and patients.

In *Preparing for Advertising and Promotion eCTD Submissions*, **Georgina Lee** and colleagues provide the sponsor's perspective and best practices on facilitating electronic common technical document (eCTD) submissions for promotional materials. The authors address the advantages of drawing on vendor support and internal training to support eCTD submissions and share useful checkpoints for when considering vendor support. They emphasize how being open minded and flexible during the set-up and maintenance processes can help ease the transition to, or initiation of, eCTD submissions for promotional materials across cross-functional teams.

Starting out in ad promo

It's been a year of new insights and lessons learned, mostly related to the COVID-19 pandemic. But for **Rene Rabaza**, the most important lessons came out of her first year in ad promo. In *10 lessons learned during my first year in ad promo*, Rabaza emphasizes the importance of learning through reading, building relationships, explaining your standpoint on a subject, strategizing and communicating, and asking questions – lots of them, she emphasizes. Rabaza also offers advice on how to achieve those goals. The article is geared to ad promo newbies, but all regulatory professionals could benefit from reading this article.

Upcoming in 2021 *Regulatory Focus*

What's coming in January?

Articles during January 2021 will focus on a range of topics examining the impact of disruptions such as COVID-19 on the global regulatory community, including best practices for meeting remotely with health authorities; comparison of onsite to virtual GMPs; keeping clinical trials on track; third party reviews; monitoring quality and compliance; as well as new implications for work style; developing the next generation of staff; finding new employment during COVID. Look for these topics and more throughout January at Regulatory Focus.

And February?

For February 2021, Regulatory Focus will look at Global Regulatory Harmonization. The submission deadline for articles has been extended to 15 January 2021. To contribute an article, contact Renée Matthews at rmatthews@raps.org. Articles will be posted throughout February at Regulatory Focus.

Issue description Harmonization, convergence and reliance are becoming increasingly important in regulatory affairs. As molecules become more complex, the boundaries between different types of therapeutic products blur and national regulatory authorities (NRA) are stretched with the necessary expertise to review all these new product innovations. One response by NRAs is to develop work-sharing arrangements and some of these initiatives will be covered in this topic. However, work-sharing cannot occur without international adoption of technical standards, so we will also examine the progress occurring in this area, particularly with respect to adoption of ICH standards globally.

Call for articles

For March

For March 2021, *Regulatory Focus* will look at Regulatory Intelligence. The submission deadline for articles is 1 February 2021. To contribute to the March issue or suggest a topic, contact Renée Matthews at rmatthews@raps.org.

RF Quarterly

Regulatory Focus is launching the *RF Quarterly* series this Spring to replace the former article series. Each *RF Quarterly* will include original content developed around a quarterly theme as a member-exclusive addition to regular monthly features. The themes for 2021 will be:

- Global Clinical Trials (Spring)
- Artificial Intelligence in Regulatory Affairs (Summer)
- Quality and Compliance (Fall)
- RAPS 2021 Convergence (Winter)

For the Spring *RF Quarterly* focusing on Global Clinical Trials, we are seeking articles on experience with the EU voluntary harmonization procedure; implementation of the FDA guidance on patient-focused clinical development; ensuring diversity in clinical trials; real-world data and evidence, getting

alignment of FDA, EMA, and PMDA on global registration trials; reporting clinical trial changes to the FDA during the COVID-19 pandemic; approaches to first in human trials for rare/ultrarare diseases (especially with gene or cell therapy). We would also be interested in articles on topics not mentioned here, but that fall within the broader context of the issue theme on global clinical trials.

To contribute to the Spring *RF Quarterly* or recommend a topic, please contact Renée Matthews at rmatthews@raps.org.

The submission deadline for articles is 1 February 2021. Author Guidelines are available here.

Thank you for your support during the past year and for sharing our passion for regulatory advertising and labeling. We hope you find this issue informative and inspiring. We wish you well over the holidays and a healthy, safe new year.

About the author

Moulakshi Roychowdhury, PharmD, JD, is a member of the RAPS Editorial Advisory Committee. She was co-lead for the December issue with fellow EAC member, Linda Pollitz, RAC.

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