SATORI CONSULTING

SOCIAL MEDIA AND REGULATION

Part I: Pharmaceutical and Life Sciences

Finding opportunity in new regulation

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BACKGROUND

Introduction

Social media have the potential to efficiently engage hundreds of thousands of consumers and add enormous value to any marketing portfolio. But as the possibilities and risks of these media continue to unfold, outdated regulatory frameworks are being challenged: regulators are realizing that they must uphold established regulatory principles while attempting to address the unique risks characteristic of social media.

While the pharmaceutical and life sciences industry awaits the FDA's guidance on the promotional use of social media[1], manufacturers need to manage their regulatory risk and ensure the near and medium-term competitiveness of their global marketing programs by anticipating the FDA's requirements. This article, based on our experience in the field, will explain how manufacturers can find opportunity and manage risk within the coming regulatory environment.

The Expansion of Regulatory Oversight and Authority

In recent years, legislative acts and amendments have provided for an unparalleled expansion in the FDA's regulatory purview and powers. The FDA is now mandated to investigate more entities more frequently, has the power to force product recalls, and has expanded postmarketing study and surveillance requirements. The combination of a more active and stringent regulator with increased scope and powers implies a profound shift in the regulatory landscape.

However, the various forms of regulatory expansion have generally not been matched by an increase in agency budget. Consequently, the FDA has looked to leverage novel methods and technology for fulfilling its mission and expects more proactive compliance from manufacturers, thereby further increasing the demands of the current regulatory environment.

The expansion in regulatory oversight and authority is also a response to the increasing risks that face the American consumer as manufacturers increasingly utilize source and manufacture globally. Over 40 warning letters were issued by the FDA in 2012-13 addressing this problem of inadequate manufacturing standards and processes. However, the shift is also a response to the emerging forms of interaction between manufacturers and consumers that necessitate an expansion in existing regulation, and which actually provide an opportunity for regulators to better fulfill their mission statements by leveraging ever larger data sets giving new insights into drug usage and results.

Recent Regulatory Action

Recent examples of regulatory action help to illustrate this framework of global regulatory expansion:

In the new regulatory environment, large fines are clearly being leveraged to deter non-compliance. In June 2012, EMA acted upon Roche for 80,000 cases of inadequate pharmacovigilance related to a patient support program. Roche may be fined up to 5% of its EU revenue. Satori's involvement in FDA efforts can attest to a similar increased stringency in the United States regarding the robustness of manufacturers' pharmacovigilance operations.

Beyond merely financial deterrents, regulators are looking to make structural changes to increase manufacturer compliance. For example, in November 2013 Johnson & Johnson settled civil and criminal allegations for $2.2 billion related to off-label promotion of drugs between 1990 and the early 2000s. In

[1] Which is due July 9, 2014

addition to the fines, Johnson & Johnson entered into an agreement with the government "requiring the company to change its executive compensation program so it can recoup money from employees who engage in misconduct."[2] Since 2009, the Justice Department has recovered over $12 billion through the False Claims Act for fraud against federal health-care programs.[3]

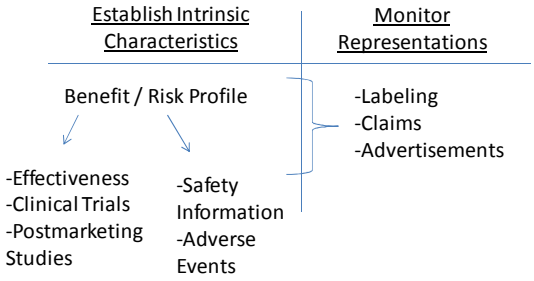
It is less obvious how the above events relate to Novartis' social media policy. A visitor on the Novartis Facebook page will encounter a Community Guidelines section explicitly prohibiting communications that meet the following conditions (among many others):

- If your posts are product related
- If your posts offer health or medical advice
- If your posts contain any personal information such as your email address or phone number

It is strange that these elements would be excluded from a consumer's online conversation with a manufacturer since concerns about health and product usage are the *raison d'être* of manufacturers, uniting the manufacturers and consumers in an online community. Ultimately, Novartis' social media policy is an attempt to manage its regulatory and reputational risk. But to understand how this media strategy relates to the regulatory action against Roche and Johnson & Johnson, we need to understand the FDA's mission and articulate the uniqueness of social media.

Appropriate Response: Think like a Regulator

Understanding a regulator's core mission enables manufacturers to mitigate risk and anticipate regulatory actions. As it pertains to this article, the FDA"s essential mission is to ensure the safety and effectiveness of drugs, ensure the correct labeling of products, and advance the public health by helping to speed product innovations. All of its other efforts can be derived from this mission statement, and are organized around two primary domains: establishing and maintaining the Intrinsic Characteristics of a drug, and monitoring the Representation of these characteristics



Establishing the Intrinsic Characteristics of a drug means understanding its benefit/risk profile. If the risks are too high for a given benefit, then the FDA will prevent the use of the drug for that benefit (viz., off-label use). Conversely, if the benefit is very high, and if the drug is far more effective than comparable existing therapies, the drug may obtain expedited marketing privileges despite a lack of complete understanding of the associated risks (in order to accelerate innovation and improve the public's health). In general, once the Intrinsic Characteristics are well understood through clinical trials and postmarketing studies, the drug may receive a full license to enter interstate commerce and its label will reflect these Intrinsic Characteristics.

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[2] http://www.washingtonpost.com/national/health-science/johnson-and-johnson-agrees-to-pay-22-billion-in-drug-marketing-settlement/2013/11/04/a7092342-456a-11e3-b6f8-3782ff6cb769_story.html
[3] ibid

New safety information is therefore extremely important because it may alter the benefit/risk profile of a drug, thereby requiring a re-evaluation of its licensing and potentially requiring a change to its label. The FDA is strict with labels and advertising claims because these must accurately reflect the drug's Internal Characteristics. Misrepresentation of the Internal Characteristics is a misrepresentation of the benefit/risk profile established and ensured by the FDA and seriously misleads the consumer. Clearly, protecting consumers from adulterated and counterfeit products follows from the FDA's mission to ensure the benefit/risk profile of products.

CHALLENGES

Uniqueness of Social Media

Despite the lack of official guidance on the use of social media for promotional purposes, the FDA has given hints about its perceptions of these media. In particular, the FDA has articulated several aspects of these media which are unique and cause for concern:

1. Public character of the medium
2. Relative permanence of the medium's content
3. Subtle interactions which may implicitly transgress FDA regulations (including "liking" and even the tone of manufacturer content)[4]

These three aspects are joined by three more common considerations in customer interactions that the FDA regulates:

4. Fair and balanced advertising
5. Promotion of off-label drug use
6. The potential for reports of New Safety Information

Understanding these elements will help manufacturers develop practices that institutionalize good behaviors even before official guidance is released. For example, recent FDA guidance on off-label drug use and social media allows manufacturers to provide accurate drug information to consumers in private, but not in public. This is because the near-permanence of social media content entails the possibility that a consumer will find outdated drug information that might not reflect all up-to-date safety information, and thus not reflect the currently established and ensured benefit/risk profile.

Understanding the Regulatory Action

One is now in a position to understand the interrelation of the above cases involving Roche, Johnson & Johnson, and Novartis. Roche was fined for its lack of reporting new safety information which would have likely altered the benefit/risk profile of the drug and required label changes due to the severity of the adverse events that went unreported. Johnson & Johnson, among other fraudulent activity, was fined for the promotion of off-label drug uses, i.e., uses for which there is an unacceptable benefit/risk profile.

The Novartis case is most similar to that of Roche in its relation to safety reporting. Novartis' social media policy is intended to minimize the organization's risk by accomplishing three things: prevent the public reporting of new safety information, protect the reputation of its products, and minimize the amount of safety reporting that takes places in order to maintain its established benefit/risk profiles ensured by the FDA.

[4] http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf

Safety Dominated Strategy

The Novartis example demonstrates a common social media strategy among manufacturers, one which evinces an imbalance between Safety and Commercial considerations. This strategy greatly restricts the activities of marketing teams and misses out on the full potential of social media, effectively excluding the "social" from social media. In the risk averse strategy, consumers are unable to openly discuss important medical issues with the manufacturers that are responsible for their good or bad health outcomes.

There are logical reasons for the risk-averse strategy: it limits the manufacturer's regulatory liability for safety reporting, protects its brand reputation if one expects adverse events to be reported, and limits the costs associated with full-time monitoring of marketing programs and the infrastructure needed to support them. However, this is ultimately a losing strategy. Those adopting it will suffer a competitive disadvantage in the near- to mid-term as other manufacturers fully engage with social media to market their products.

Furthermore, it's clear that engaging in the opposite strategy is not ideal either. An unfettered commercial strategy will expose the manufacturer to enormous regulatory and reputational risk.

STRATEGIC SOLUTION

Designing a Commercial/Safety Balanced Strategy

The most successful manufacturers will adopt a strategy of openness and transparency with consumers, responding to and taking responsibility for their problems and concerns. For example, a yearly survey of over 33,000 consumers in 27 countries has shown conclusively that frequent communication and openness with consumers is the most important factor in driving reputational benefits for an organization.[5]

Commercially, developing brand loyalty is a strong competitive advantage allowing companies to potentially increase market share and maintain higher prices in competitive markets. However, adopting a transparent position with consumers and engaging with them in important and difficult conversations will ultimately allow proactive companies to create better products by utilizing better information from a larger population of consumers: a beneficial outcome for both Safety and Commercial respects.

This firm-wide strategy will require global standardized processes for managing and responding to this new and better information from worldwide consumers. The implementation of these processes should not be seen as a burden, but as an opportunity whose urgency can be leveraged for establishing standardized risk management processes, obtaining detailed performance statistics about global marketing programs, and discovering more scale economies through efficient and competitive support structures.

The Regulatory Horizon: Safety Reporting, Technology, and Proactive Manufacturers

The new regulatory horizon also entails a transition to an atmosphere of more proactive surveillance and reporting, heralded in many ways by new tools like "Google Flu Trends," which tracks Google searches related to Flu symptoms to predict outbreaks. The FDA is currently soliciting proposals for its own implementation of tools that can scan social media for real-time reports relating to outbreaks and adverse events.

The resource-constrained FDA has already expressed significant interest in utilizing all forms of information available to maintain the benefit/risk profile of drugs and receive advance notice of any possible outbreaks or manufacturing defects. Twitter, Facebook, and all other forms of engagement between manufacturers and

[5] Edelman PR Trust Barometer: http://www.edelman.com/insights/intellectual-property/2014-edelman-trust-barometer/about-trust/global-results/

consumers will be leveraged to rapidly obtain more and better safety information and expand the FDA's ability to monitor and ensure the safety and effectiveness of drugs.

Consequently, manufacturers should expect increasing pressure or even requirements from the FDA to proactively engage with consumers and leverage new technology to aid the FDA in ensuring the safety and effectiveness of drugs. Manufacturers that anticipate this change and thus have the time to implement robust and efficient processes will have a strong competitive advantage over those who do not.

Conclusion

Satori's involvement in the Industry and with Regulators has made it clear that the coming regulatory environment places far greater responsibility on manufacturers to be proactively compliant and that safety reporting has moved into the foreground of Regulator's concerns.

The best approach for manufacturers in this environment is to find and capture the opportunity hidden within the new regulatory regime to strengthen your corporation's Safety and Commercial competitive positions while mitigating risks of unexpected regulatory actions or changes.

Understanding and anticipating the FDA's actions in this shifting regulatory horizon will enable manufacturers to gain a competitive advantage by implementing commercial/safety balanced marketing strategies early in order to maximize the value of social media. Implementing this strategy correctly will result in improved corporate reputation, brand differentiation, and increased market share.