EXECUTIVE SUMMARY

RX TO OTC SWITCH SUMMIT
Assessing the Future of Switches in the US and Beyond

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Group: RX to OTC Switch Forum
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INTRODUCTION

HERE’S WHAT YOU MISSED AT EXL PHARMA’S RX TO OTC SWITCH SUMMIT

If you weren’t able to join us in 2014, here is what you missed at ExL Pharma’s Rx to OTC Switch Summit, the only event covering a switch from end to end.

With a focus on assessing the future of switches in the United States and beyond, the one-of-a-kind Rx to OTC Switch Summit, held December 4-5, 2014 in Philadelphia, provided a comprehensive overview of marketing trends, cutting-edge technology and regulatory development as well as lessons learned from past switches.

The market potential for switches is huge, and the FDA is actively working with industry stakeholders to look into new classes and accelerate switches. Most “easy” switches have been done, so the next hurdles can only be tackled if the industry successfully collaborates with pharmacists, retailers, physicians, patients, ACOs, payers, the government and technology experts. The summit brought together switch experts from Pfizer, Bayer Health Care Consumer Care, Sanofi-Chattem, Novartis, Johnson & Johnson, Reckitt Benckiser, BD Medical, the American Pharmacist Association, Penn State University College of Medicine, the American Academy of Nurse Practitioners and many other organizations.

The event featured panel discussions on best practices to interact effectively with the FDA when applying for a switch; collaborative workshops on enhancing switch strategy; roundtables to discuss lessons learned from various switches; presentations on subjects like leveraging social media for patient adherence and the regulatory switch landscape in the United States and around the globe; and much more.

The Rx to OTC Switch Summit was designed for pharmaceutical, biotechnology, medical device and healthcare professionals who have already switched products; those who are currently undergoing a switch; and those who potentially forecast a switch down the road.

The following are session summaries and highlights to give you an idea of what you may have missed at the Rx to OTC Switch Summit.
The day one pre-conference workshop from Susan Levy of Susan Levy Consulting centered on ways to “Explore Switch Strategy and Develop a Road Map for a Successful Switch.” Levy stated that a switch is all about risk versus benefit. Assuming that safety and efficacy have already been demonstrated in an Rx setting, the next step is to determine if a consumer can safely use the drug without the presence of a learned intermediary, putting the focus on consumer behavior as well as on adequate and appropriate labeling. She said that basic switches do not exist and that no two switches are the same. The process itself involves meeting with the FDA, conducting label comprehension and self-selection studies, filing an NDA, and attending an Advisory Committee meeting. Rx to OTC switches accounted for 13 percent of sales and 26 percent of growth over the past five years. The successful switch of new and more challenging categories may require the ability to use and validate non-traditional communication methods to aid consumers in making more complex choices. Further, facilitating self-selection and use decisions can be accomplished with the PDF, DF and help lines; CDs; user guides; support materials; and so on. It may also require more dialogue between the agency and sponsor to assure safe use when using new tools. Drivers of switches include Rx factors (size of Rx, DTC impact and the role of managed care), order of entry, satisfaction with current category choices, professional marketing, and excellence in execution. Strong retail partnerships are critical to initial success.

David Lee Scher of Penn State College of Medicine delivered a presentation focusing on “Leveraging Technology to Ensure Safe Use.” Mobile apps, analytics and remote patient monitoring tools are all game-changing technologies in the industry today. Mobile medical apps can provide patient/caregiver safety education, pill identifier information, medical adherence and more. Pitfalls of designing a medical app, however, include a lack of clinician involvement, poor attention to usability, and a lower level of knowledge regarding the healthcare landscape and/or regulatory requirements. Barriers to adoption include incomplete regulatory guidance, lack of reliability, lack of comprehensive mobile strategy, physician fear and more. In addition, sensor technologies now offer a wealth of safety benefits. Going forward, pharma must incorporate digital technologies in any Rx to OTC safety strategy.
Tamar Yarkoni of Sanofi offered a presentation titled “So the Prescription Product I Support Is Going Over-the-Counter, Now What?” Yarkoni noted a strong case for OTC: 81 percent of US adults use OTC treatments as a first response to minor ailments, and for every $1 spent on OTC meds, there is a $6-7 savings for the US health system. In addition, OTC meds provide $102 billion in value to the US healthcare system annually. Entities that affect a switch include the consumer, the government and companies. Pros for OTC use include DTC advertising, convenience, affordable cost, empowerment and consumer trust, while cons include a lack of medical knowledge on the part of the prescriber and the potential need for medical help if a problem persists or worsens. Consumer-friendly labeling is very important, and the intended uses, directions and warnings must be written so clearly that even consumers with low reading comprehension can understand them. Recent Rx to OTC class switches have involved smoking cessation, diarrhea, heartburn, yeast infections, allergies, overactive bladder and sleeplessness. Consumer-friendly responses are crucial, as is communication among departments and training on the disease state. You may encounter challenges when creating a comprehensive database for consumers, explaining to a consumer why your product is OTC while others in the same class are not, maintaining standard responses for HCPs, and dealing with a lack of insurance coverage.

Jan Towers of the American Academy of Nurse Practitioners and Tom Menighan of the American Pharmacist Association engaged the audience in a panel on how to “Collaborate with Retailers, Pharmacists and Other Stakeholders to Ensure Safe Use.” Towers and Menighan They discussed their roles in the industry and the importance of working toward shared accountability while offering innovative ideas to ensure patient safety and comprehension. Since the introduction of NSURE in 2012, the FDA has not indicated whether it will create a regulatory framework specific to NSURE (Nonprescription Safe Use Regulatory Expansion). In fact, the FDA has indicated that it is open to novel ideas in switch applications. Further defining their roles, Towers noted that nurse practitioners today provide and treat independently in all 50 states and the District of Columbia and have a similar perspective to physicians with a focus on safety and continuum of care. Menighan added that pharmacists are ideally situated help ensure safe use for innovative switch ideas and increasingly provide patient care services. During any switch, the process for safety and clinician oversight must be carefully considered. More stakeholder education, as well as standards for safe dispensing/utilization and public education, are still needed.
“Applying a Patient/Consumer-Centric Approach in Drug Development” from Roseanne Rotondo of Novartis Consumer Health, Inc. focused on identifying what patients want and including real-life considerations into product development to maximize success in the long run. She noted that collaboration is the key to success where the consumer is at the center of every conversation. Likewise, knowing your target population is important with diverse consumers. Consumer-centric measures include understanding a variety of factors: perceived value versus measurable medical outcomes, the consumer’s feelings before/during/after product use, consumer confidence about self-selection, and the consumer’s experience when using product. (Was it easy or difficult to use?) Likewise, it is critical to engage physicians and pharmacists early in the process. These measures create a win for everyone involved.

Bernie Simone of Chattam provided details on the “Architecture of a High-Performance Switch Team.” Switches can provide lucrative business opportunities, but require more resources than typical OTC line extensions and as well more time and investment. In addition, switches can be risky and approvals are infrequent. An experienced and properly structured switch team can help reduce risk, hasten the switch timeline, minimize total investment, and maximize business potential — hence its importance. A well-structured switch team will include a development team, a commercial team and an operations team, all of which are preceded by a business development team that establishes the complete scope of leadership responsibilities. Naturally, switch complexity will drive the need for additional resources. Further, switch experience at key functions is critical to timing, costs and overall success. To achieve high performance, teams should strive to develop an action-oriented project governance plan, inspire a strong work ethic and shared culture, institute project planning principles, and maintain team continuity. Other influential steps include integrating the voice of the customer and keeping the focus on the label.
Dave Hilifiker of Johnson & Johnson offered a session on how to “Understand Recent Regulatory Developments in the US and Beyond.” Since 2013 saw the FDA’s approval of two new types of drugs for new OTC indications, Hilifiker argued that all of the “easy” switches have not been done. He said that actions to improve access across Europe and North America are continuing, while Asia and South America are just getting started. Since the goal of NSURE, or Nonprescription Safe Use Regulatory Expansion, is to improve public access to medications by Rx to OTC switch under certain conditions of safe use, Hilifiker argues that the sky is the limit. Yet approval with conditions to ensure safe use has only been authorized for prescription drugs; for a drug to qualify for Rx exemption, the FDA must find “the drug is safe and effective for use in self-medication as directed in proposed labeling.” Nevertheless, the FDA cannot make this happen on its own, and other stakeholders (pharmacists, payers, physicians, etc.) will need to seed change in their environment as well. Likewise, technology opens up a whole new world (and creates several challenging questions as well) when it comes to Rx to OTC switches.

UPCOMING EVENTS

2ND RX TO OTC SWITCH SUMMIT
December 2015, Philadelphia, PA

RX to OTC Switch Summit will allow you to network with colleagues while exploring the switch process from beginning to end. Whether you are playing with the idea of tapping into the very lucrative OTC marketplace or are an expert in the field, this conference assesses the current switch landscape in the US and beyond. It also provides a comprehensive overview of marketing trends, cutting-edge technology and regulatory developments, and is a forum for discussing lessons learned from past switches.

For more information please visit www.exlevents.com/rxtootc or contact Scott Grossman at 917-258-5152 or sgrossman@exlevents.com.
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