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MARKETERS IN WHITE COATS

Think generics is limited to ANDAs and patent challenges? Think again. Marketing and R&D must work together on creating the value proposition of the product, just like in brand pharma, writes **Kathy Kovalic**

If you've only worked in brand pharmaceuticals, the view that you take of the generic development process may be limited to just ANDAs (Abbreviated New Drug Applications) and patent challenges. But in reality, there are quite a few opportunities to enhance a generic's value proposition beyond the originator drug.

For this to occur in generic pharma product development, it is critical for the Marketing and R&D teams to be in lock step with each other regarding product-development strategy, defining roles and responsibilities, and executing timelines.

Marketing needs to explain what the customer market looks like, what are the unmet needs of those customers, and how the team can solve those problems together. R&D members need to explain what they need from Marketing in order for them to be successful, and what kind of data is important.

The best way for these two groups to gel is to set up cross-functional teams. These are critical to the overall generic drug-development process. The following disciplines should be included:

■ Regulatory Affairs: to assess potential filing strategies. If there are patents listed in the Orange Book, what is the potential filing strategy? Certifying paragaphs I-IV? Have your Regulatory team role play FDA, and be the devil's advocate to ensure the latest guidances or potential guidances are included or ask the potential questions that FDA could come back with.

■ Medical and clinical: to understand if any clinical trials are required as in the instance of introducing a new strength in a particular drug, one that may not exist in the brand but makes sense from a prescribing or dosing perspective, as it could present an opportunity to give the generic the edge over the competition.

■ Legal: to assess if there are patents that R&D needs to be aware of and answer other questions. What is the rate limiting patent? Is

it on the drug substance? Is our formulation clear of any potential infringement claims?

■ Strategic purchasing: to ascertain whether or not generic raw material is available and to determine the following: Who is developing the Active Pharmaceutical Ingredient (API)? When will it be available for R&D to start evaluating the formulations?

By including the above disciplines with the Marketing and R&D teams, it allows for open discussion, definition of risks, potential opportunities to differentiate your product, and the development of timelines. Timeline development is critical in the generic drug arena; you must be there when the market forms. Otherwise, you may miss your opportunity to pay back your development costs in a timely manner.

Money is made in the first 90 days of generic drug product launches. That is when the prices are the highest and you have your best opportunity to partially pay back your development costs.

Marketing should bring the following: market data, preliminary forecasts, preliminary price sensitivity models, and feedback from the clinicians who will use the end product. Feedback from your sales team is also necessary, as they can help with best positioning the product. It is almost as if you are prewriting your marketing plan.

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I have found that providing solid market background helps with the creative thinking of the teams. Getting alternate or challenging opinions can make the product a strong winner in the face of multiple generics.

Marketing and R&D should work together on creating the value proposition of the product—it is not just a marketing function. When interdisciplinary teams work together to solve clinician problems, even with generic drugs, you can build a solid platform for your product. That way, all the disciplines win since they had input and had a piece of the success of the product.

Invite R&D to focus groups during the development phase, so they can see for themselves what the clinical need is

R&D though, must deliver on the timelines. There is no value, or very little value, in being late. In today's generic market, there can be multiple players receiving FDA approval on the date of the patent expiration.

It is also important for R&D to be creative and to think outside the box. What other opportunities exist to enhance the product? Is there opportunity to improve the formulation, such as develop a room-temperature product versus a product that needs refrigeration? Cold-chain storage and delivery can be very costly and reduce the margin on the product.

Packaging changes can also provide a boost. Can the formulation be enhanced to avoid the need for additional overwrap to protect from light? Is the product oxygen sensitive? What can be done to address that issue?

All the while, keep in mind that you are working on a generic and need to be careful that you could significantly change the filing from an ANDA to a 505(b)(2). Or there are so many changes that you would need to run clinical studies like safety or bioequivalence to ensure you have not significantly changed the originator drug.

All of these areas can be addressed with the cross-functional development team. Ask questions, learn from each other. Invite R&D to focus groups during the development phase, so that they can see or hear for themselves what the clinical need is that the clinician is trying to meet or solve.

Take R&D personnel to a customer site—if you are working on hospital-based drugs, take some of them to a real hospital pharmacy. Let them see how business is done. Let them see how patients are treated. How does the pharmacist and his/her teams address patient care and needs on a daily basis?

Take them up to the nursing units—how do the nurses do their jobs? What can be done to make their life easier, thereby making the patients more comfortable during their stay? If your world is retail pharmacy, take your R&D counterparts to see how a retail pharmacy works. Once you come back from a customer visit, reassess the path that you may have originally planned out; does it make sense from a user perspective? Did you solve a problem, or did you create one?

Once you incorporate all of these aspects into your generic drug-development process, imagine the possibilities. Speed to market and low cost are still key. Although customer visits and focus groups are important and can be great educational opportunities, there are still patents to overcome or challenge, drugs to develop, FDA submissions and timelines to meet. Also, not every drug warrants a deep dive, but having that experience can certainly help future development thought processes.

Work with your R&D counterparts and your cross-functional teams. Take the opportunity to challenge and educate each other to make your drug-development process an amazing success. There will always be another way of thinking about a product. It is not always the job of either Marketing or R&D—all of you together make a product successful. ■

Differentiating a copy

Tinker with a generic too much, you may change the filing to a 505(b)(2). Change nothing, you risk losing out to other generics. Here are some potential changes or aspects to consider, to gain an edge.

Change/Aspect	Edge	Discipline
New strength	May not exist in brand but makes sense from prescribing or dosing perspective	Medical/clinical
New formulation	A room-temperature product vs. one that needs refrigeration can improve sales margin	R&D
Customer visits	By letting R&D see how business is done, you may reevaluate the path to market	Marketing/R&D

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