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How to increase biosimilar access and commercialization success

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The workshop will be an interactive exercise to impart lessons learned in a successful rollout of biosimilar access and commercialization strategies to the targeted stakeholders. Specifically, this workshop will focus upon strategies and tactics to be utilized by successful firms entering the biosimilar space. These different approaches will consist of but not be limited to actively engaging with payers, key opinion leaders (KOLs), patient support groups, and internet applications. After completing the workshop participants will be better able to compose, implement, and engage specific strategies to ensure success within their respective markets. Launching biosimilars will be a challenging task for the innovative firm. One must be clear that the strategies and tactics of firms launching and commercializing generics will only be partially applicable to the biosimilar niche. For instance, generic product launches comprise a 180-day opportunity for first to file applicants. Specifically, the firm that was first to file has an added advantage over its competitors. They compete head-to-head with the originator and introduce price cuts for the said product. This strategy has been applied in most cases in all markets where competition occurs. Pricing may tend to stabilize at some point because the originator might refuse to keep lowering current pricing and settle for a percentage of the market. The innovator will recognize this and will feel no further obligation to keep lowering its price. The additional competitors entering the market after sitting out the required 180-day period will launch their products and as a way of gaining market acceptance will immediately lower pricing in order to gain a foot-hold into the market. It is not unusual to witness a 70+% drop from the original price of the product enjoyed by the originator. This pricing strategy works well for chemically equivalent generic product offerings because substitution can readily occur. Conversely, biosimilars are a much different story in terms of composition, equivalency, and commercialization. For instance, biosimilars are constructed from living cells and their composition is not identical such as chemical entities but rather similar, hence the term biosimilar, follow-on-biologics, etc.. and as such must be treated accordingly. Therefore, phase I, PK/PD, and phase III studies must be conducted to demonstrate similarity and equivalency in order that the regulatory authorities will sign off on the product offering to be launched in the respective marketplace. In terms of biosimilar product substitution, firms can opt in and conduct additional switching studies to achieve this designation. Firms must make the decision to conduct this extra step that will add time and additional costs prior to launch and commercialization efforts. What er are finding is that firms would rather not forgo tis added expense and delay to get to market. Given this scenario biosimilar firms must deploy sophisticated personnel to create a number of strategies and tactics similar to what brand firms must undertake. For example, for these firms to become successful they must not employ the standard generic business model of pricing and substitution but rather must actively engage with payers, key opinion leaders (KOLs), patient support groups, and internet applications. This is a major strategy change and the resulting tactics must align to what is acceptable and customary within such commercialization spaces. As was mentioned this workshop will focus upon strategies and tactics to be utilized by successful firms entering the biosimilar space. These different approaches will be analyzed in order that participants will be able to compose, implement, and engage within their respective markets.

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