Understanding purchasing patterns and product access of newly launched specialty generics

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INTRODUCTION

Specialty pharmacy is anticipated to continue its rapid growth trajectory into the foreseeable future with projections of reaching $500 billion in expenditures by 2020. In addition, 80% of new drug approvals are in specialty therapeutic categories. Specialty drugs currently represent less than 2% of the prescription count, but represent nearly 40% of spend.[1] Due to an increased focus on the development of specialty drugs, the expansion of new indications for existing specialty medications, and the continued focus on personalized medicine and limited distribution drugs that will likely fall under the specialty channel, there is more focus than ever on the cost and access of specialty medications.

Historically, there has been much discussion of biosimilars in the specialty pharmacy space, but few discussions of specialty generic opportunities created through FDA approval via the abbreviated new drug application (ANDA) pathway. However, the conversation around specialty generics is evolving as several high profile specialty drugs have lost patent exclusivity and even more specialty generics are anticipated in the future. Furthermore, payers and patients continue to look for ways to manage health care costs for specialty medications and specialty generic products can offer opportunities for significant savings. According to the FDA, generic drugs saved the US health care system $1.67 trillion from 2007 to 2016.[2] Considering the high cost of specialty drugs, specialty generic savings opportunities are anticipated to be significant.

Given the increasing interest in specialty generics, manufacturers are expected to invest more than $100 billion in their development over the next five years.[3] To remain competitive, pharmacies must have access to purchase and dispense specialty generic products and also ensure that they are accessing competitive pricing to purchase the growing number of specialty generics. One way in which to do so is for the pharmacies to access pharmaceutical manufacturer agreements through MHA Specialty Pharmacy Solutions for access to and pricing for specialty generic drugs.

OBJECTIVE

Given the expansion of specialty generic approvals in the marketplace, this study was conducted to help understand purchasing patterns of newly launched specialty generics. In addition, this study sought to determine whether or not increased access to a specialty treatment was facilitated by the entrance of a specialty generic product.

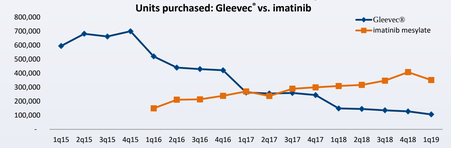
METHODS

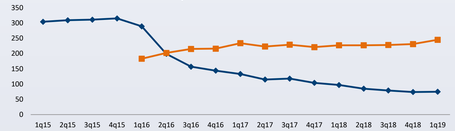
To determine purchase patterns of newly launched specialty generics, the rate of change of both the brand and generic products were measured for five specialty drugs across a subset of pharmacies purchasing through MHA agreements. The brands and their corresponding generics included in the study were: Gleevec® (imatinib mesylate); Makena® (hydroxyprogesterone caproate); Zytiga® (abiraterone acetate); Xenazine® (tetrabenazine); and Ampyra® (dalfampridine ER). When possible, the brand rate was measured by the units of brand product purchased the quarter prior to the generic launch compared to the number of units purchased in 1Q19. For Gleevec®, the calculation was done 4Q15 through 1Q19; for Makena®, the calculation was done 1Q18 through 1Q19; and for Zytiga®, the calculation was done 2Q18 through 1Q19. This calculation was not possible for branded Xenazine® and Ampyra® given that no pharmacies in the study were able to purchase these limited distribution drugs through a wholesaler. The generic product rate was measured by the units of generic product in the quarter it launched compared to the number of units purchased in 1Q19 and was calculated for all five study products. For imatinib, the calculation was done 1Q16 through 1Q19; for hydroxyprogesterone caproate, the calculation was done from 2Q18 through 1Q19; for abiraterone acetate, the calculation was done from 3Q18 to 1Q19; for tetrabenazine, the calculation was done from 3Q15 to 1Q19; and for dalfampridine ER, the calculation was done from 3Q18 to 1Q19.

To detect changes in product access to specialty generics, the number of corporations purchasing the brand was measured in the quarter prior to the generic launch compared with the number of corporations purchasing the generic in 1Q19. Changes in the number of corporations purchasing the branded product and the generic product were also tracked over time.

RESULTS

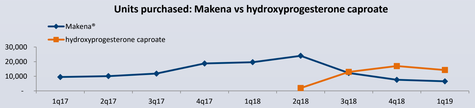
Gleevec® vs. imatinib mesylate

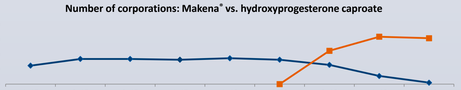




Gleevec® number of units decreased 80% while generic imatinib unit purchasing grew by 134%. The number of corporations dispensing generic imatinib increased 34% while the number of corporations purchasing Gleevec® decreased by 76%. When compared to the number of corporations purchasing the brand, the number of corporations purchasing imatinib decreased by 22%.

Makena® vs. hydroxyprogesterone caproate

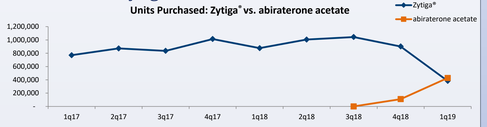




Makena® number of units decreased 67% while generic hydroxyprogesterone caproate unit purchasing grew by 641%. The number of corporations purchasing generic hydroxyprogesterone caproate increased 38% while the number of corporations purchasing Makena® decreased by 94%. When compared to the number of corporations purchasing the brand, the number of corporations purchasing hydroxyprogesterone caproate increased by 77%.

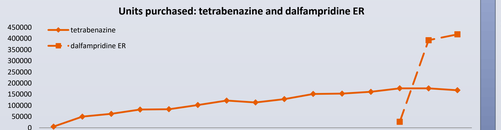
RESULTS (Continued)

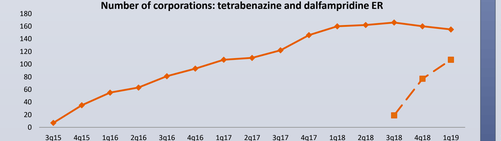
Zytiga® vs. abiraterone acetate



Zytiga® number of units decreased 63% while generic abiraterone acetate unit purchasing grew by 289%. The number of corporations purchasing generic abiraterone acetate increased 60% while the number of corporations purchasing Zytiga® decreased by 36%. When compared to the number of corporations purchasing the brand, the number of corporations purchasing abiraterone acetate increased by 6.1%.

tetrabenazine and dalfampridine ER





Tetrabenazine number of units increased 2967% and the number of units of dalfampridine ER purchased increased 1451%. The number of corporations purchasing tetrabenazine grew 2967% and those purchasing dalfampridine ER increased 463%. There were no pharmacies in the study who were purchasing brand Xenazine® and Ampyra®.

CONCLUSIONS

This study revealed that specialty generic products are very quickly adopted in the marketplace. Particularly steep uptake was noted in those products that have launched specialty generics more recently (2018 in the cases of hydroxyprogesterone caproate, abiraterone acetate, and dalfampridine ER), suggesting that there may be an increased comfort level and desirability for quickly adopting specialty generics presently as compared to those products which launched several years ago (2016 in the case of imatinib and 2015 for tetrabenazine), which showed slower growth curves.

This study also determined that for every product except imatinib, access to purchase, and therefore dispense, the specialty treatment was increased after the launch of the generic as measured by the number of corporations purchasing the generic in 1Q19 compared to the number of corporations purchasing the brand the quarter prior to the generic launch. It is hypothesized that growth was not seen in the imatinib group due to newer, more potent tyrosine kinase inhibitors entering the market.[4] Increasing access to specialty generic products allows the pharmacy to remain competitive, service additional patients and referral sources, and continue to grow in the specialty space. This increased access is particularly important in the cases of limited distribution products where pharmacies may have been completely unable to access and dispense the branded versions of the specialty products, such as in the cases of tetrabenazine and dalfampridine ER.

This study illustrates that those pharmacies utilizing pharmaceutical manufacturer agreements through MHA Specialty Pharmacy Solutions were able to quickly adopt specialty generic products into their practice. Furthermore, MHA Specialty Pharmacy Solutions facilitated increased pharmacy access to many specialty products.

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