AXTRIA
INGENIOUS INSIGHTS

The Pricing Challenge of Pharma's Shift to Specialty Medicines

The Pricing Challenge of Pharma's Shift to Specialty Medicines

George A. Chressanthis, Ph.D., Principal Scientist, Axtria Inc.

> There are no **solutions**.
> There are only **trade-offs**.
>
> Thomas Sowell
>
> *Economist and Senior Fellow at the Hoover Institution, Stanford University*

There has been well-documented evidence over the last few years regarding explanations on the historical decline in pharmaceutical R&D productivity and how that trend motivated a shift in the industry toward investment focus in specialty medicines.[1-2] An increase in new drugs launched in recent years has for now reversed that long-standing trend in declining R&D productivity.[3] Many factors have contributed to this shift in product focus, despite one effect being pharma companies having to deal with rising inherent probabilities of failure in the R&D process.[2] Growing generic drug penetration (now about 90% of all dispensed prescriptions), lack of remaining viable small molecule target opportunities, growing pressures from managed care plans and pharmacy benefit managers to move patients to generic drug utilization (through bioequivalent and therapeutic generic substitution), and restrictions in future branded drug price flexibility have all contributed to the shift to specialty medicines. The shift to specialty medicines using large molecule, biologic, and genomic scientific approaches allow pharma companies to address unmet medical needs and provide for greater price flexibility due to less branded and generic drug competition.

In addition, even after the patent expirations of injectable biologic drugs, the entry of biosimilars is seen as likely more limited given the costs and expertise required for replication and acceptance by the medical community. This means branded biologics can generate a longer period of revenue post-patent expiration than seen for traditional small molecule drugs after patent expiration. The results of this shift on US drug spending are quite evident as specialty medicines now account for a significant proportion of total US drug spending, are driving the growth of drug spending, where more than half of total spending growth were on new drugs available for less than 2 years, and where oncology comprises 35% of all 2015 new drug launches and is a major driver of spending growth.[3]

However, while this shift in product focus has addressed a set of issues confronting pharma companies, it has also created a set of different problems as noted by the opening quote. Individual pharma companies have come under significant pressure for their pricing of specific drugs at the federal and state levels.[4] A recent review of pharmaceutical corporate filings and conference call transcripts found pharmaceutical sales being mainly driven by price increases, raising political concerns in Congress, and the threat of price controls, with ramifications for shareholders that this practice is not economically sustainable in the longer run.[5] This review noted that pricing being used as a driver of sales is an industry-wide issue and where recent price increases have been a significant driver of increases in US drug spending and the Medicare Part D program.[5] What is becoming increasingly evident is the growing gap between the rising cost of pharmaceutical R&D to bring drug innovation to the market[6] and individual/societal willingness and ability to pay for this

innovation.[7] Complicating this matter is the focus on specialty medicines that cater to much smaller and/or orphan drug-like patient populations as opposed primary care driven drugs. The result is the cost per patient treatment to amortize a return to the R&D investment must substantially rise, creating greater tensions with market access, affordability, and adherence. Lastly, another complex issue is financing the utilization of very expensive drugs that are used over a short time period. For example, financing drug use for metastatic cancer patients that extend life for a limited time measured in months is much more difficult, as opposed to longer-term maintenance drugs taken over years such as in the diabetes and cardiovascular disease areas. A patient may take a drug in these therapy areas for the rest of their life, spreading out drug costs and also realizing greater cost savings for payers in the benefits derived from drug use.

What then are companies to do to address the pricing challenge for costly specialty medicines? Traditional commercial model thinking that emphasizes unit sales growth will not suffice. Instead, a consideration for and demonstration of value must be infused into pricing analyses, in support of the final ultimate decision before launch, and continue throughout the entire project/product life-cycle.

Below is a non-exhaustive list of suggested company actions for the pricing of specialty medicines pre-launch:

- Start thinking about pricing / market access earlier in the project/product life-cycle. Pricing should not be an after-thought after the clinical work has been done but rather infused throughout the entire project/product lifecycle.
- Market access cost consideration should enter in as a factor to determine project target selection for further development and as a candidate for clinical trials.
- Clinical trials should be structured to quickly adapt demonstration of value propositions from results into commercial strategy and operations. This means greater coordination and information sharing between clinical and commercial teams.
- Phase 3 clinical trials of drug candidates should be measured not only against placebo but also the leading generic therapy treatment option (where appropriate) given managed care dynamics. Research-based branded drugs cannot compete against generics on the basis of cost. The only pathway for patented branded drug success over generic drugs is to demonstrate value over cost.

- Payer and individual patient affordability should play a major role in determining the economic viability when deciding whether to move forward with a phase 3 clinical trial.
- The construction of forecast simulations should be done no later than the phase 3 decision point (and then continually update beyond as new information becomes available) and the simultaneous relationship on drug pricing. This means accounting for variations in product attributes (relative to the competition), product risk profile, regulatory decision risk, market dynamics such as order-of-entry and time delay in the marketplace, managed market formulary acceptance, and individual willingness and ability-to-pay. Sales and marketing activities should be seen primarily as channels to disseminate medical information about product net value attributes to payers, physicians, and patients - not as the principal mechanisms that determine brand success.
- Performance-based pricing will become the norm for managed care contracting.[8] This means the health economics and outcomes research team will play a major role in the determination of a specialty drug price. The effectiveness of sales and marketing activities will be possible only if a price point is established that ensures optimal payer formulary acceptance, physician adoption, and patient compliance and adherence.
- Performance-based pricing contracts will require companies to leverage mobile technologies, where appropriate and that protect individual patient information, that allow for self-diagnosing and self-monitoring of patient behaviors to demonstrate product success. An added benefit of such technologies is to show patients the continuing progress and value of their drug therapy which should boost drug adherence, improve health outcomes, and lower cost of care.
- Given the high cost of specialty medicines to patients, companies need to develop cost elasticity analyses on patient out-of-pocket expenses to support the optimal development of discount card and patient assistance programs, both of which have an impact on the drug net price.

The shift to specialty medicines has opened up for pharma companies a wealth of opportunities in addressing unmet medical needs of patients and improve the cost of care. This shift has also brought significant challenges, especially in the form of pricing and market access in an environment that is becoming increasingly resistant to higher cost drugs. The keys to success will be to think differently how to prepare these drugs for market launch and the use of analytics to support pricing decisions.

References

1. Scannell J, Blankley A, Boldon H, et al. Diagnosing the decline in pharmaceutical R&D efficiency. *Nature Reviews Drug Discovery* 2012; 11: 191-200.
2. Pammolli F, Magazzini L and Riccaboni M. The productivity crisis in pharmaceutical R&D. *Nature Reviews Drug Discovery* 2011; 6: 428-438.
3. IMS Institute for Healthcare Informatics. Medicine use and spending in the U.S.: a review of 2015 and outlook to 2020. Parsippany, NJ: April 2016.
4. Rockoff J. Pricey drugs are hurdle for new biotech CEO. *Wall Street Journal* 2016; June 7: B1-B2.
5. Walker J. Drug makers raise prices despite protests. *Wall Street Journal* 2016; July 15: B1-B2.
6. DiMasi J, Grabowski H and Hansen R. Innovation in the pharmaceutical industry: new estimates of R&D costs. *Journal of Health Economics* 2016; 47: 20-33.
7. Castellani J. Keynote presentation: The changing healthcare environment. Pharmaceutical Management Science Association Annual Conference 2015. Presentation on April 20, 2015, Arlington, VA.
8. Edlin M. Performance-based pricing for pharmaceuticals. *Managed Healthcare Executive*, published online 30 September 2015, available at http://managedhealthcareexecutive.modernmedicine.com/managed-healthcare-executive/news/performance-based-pricing-pharmaceuticals?page=0,0 (accessed 22 July 2016).

George A. Chressanthis, Ph.D.
Principal Scientist
Axtria Inc.
300 Connell Drive, Suite 5000
Berkeley Heights, NJ 07922
Email: george.chressanthis@axtria.com

Contact Us

+1-877-9AXTRIA
insights@axtria.com

Disclaimer

Axtria® understands the compliance requirements behind personalization and we do not work with any personally identifiable data that can identify an end-customer of a business.

We have the strictest data security guidelines in place as we work with businesses to improve the experience for their customers.

www.axtria.com
facebook.com/AxtriaInc/
insights@axtria.com
linkedin.com/company/axtria
@AxtriaConnect

Founded in 2010, Axtria is a global provider of cloud software and data analytics to the Life Sciences industry. We help Life Sciences companies transform the product commercialization journey to drive sales growth and improve healthcare outcomes for patients. We continue to leapfrog competition with platforms that deploy Artificial Intelligence and Machine Learning. Our cloud-based platforms - Axtria DataMAx™, Axtria SalesIQ™, Axtria InsightsMAx™ and Axtria MarketingIQ™ - enable customers to efficiently manage data, leverage data science to deliver insights for sales and marketing planning, and manage end-to-end commercial operations. We help customers in the complete journey from Data to Insights to Operations.

For more information, visit www.axtria.com

Follow Axtria on Twitter, Facebook and LinkedIn