ACMA
Accreditation Council for Medical Affairs

Pharmaceutical Industry career outlook for Pharmacists, Physicians and PhD professionals.

Examining their evolving role in the pharmaceutical industry.

Contents

Where are we today?.....3
Case Study: Pharmacists.....3
Evolution of medical affairs.....4
A Universal Standard 5

Disclaimer

The information and opinions in this paper were prepared by the ACMA LLC. No part of this document may be distributed, resold, copied, or adapted without our prior written permission from the authors.

Where are we today?

Over the last decade, the number of physicians, pharmacists and scientists leaving "traditional" roles and entering the pharmaceutical industry has increased significantly. For example, recent data from the United States Bureau of Labor Statistics (May, 2016) reports that there are approximately 300,000 pharmacists. Approximately 15%-20% are employed by pharmaceutical industry manufacturers. In response to the shifting healthcare landscape and the supply/demand of pharmacists in the workforce, the pharmaceutical industry has invested significantly into a function called 'medical affairs' which employs medical and scientific professionals who hold a 'D' Degree (MD, PharmD, PhD, DO).

A major driver for this is based on the needs of their customers, namely, healthcare providers (HCPs). Increasingly, HCPs place a greater emphasis on the science, including real- world evidence to prove the value a drug or device brings to the market.

Case Study: Pharmacists

With the increased number of pharmacy schools over the past decade, the number of pharmacists has more than doubled. With this surge of pharmacists in the workforce, many pharmacists are finding it difficult to obtain attractive roles. This has created a saturated job market. Therefore, training focused on non-traditional careers such as in the pharmaceutical industry is critical as the role of the pharmacist continues to evolve.

Research has shown that exposure to a pharmaceutical industry elective course within a college or school of pharmacy curriculum may increase students' interest in enrolling in pharma advanced pharmaceutical practice experiences (APPEs) and pursuing pharma fellowships.

Additional training for pharmacists is not new in the profession (it is important to note that there is a distinction between residency as a "practical training" versus "certification" which is knowledge based and normally subsequent to practical training). In relation to clinical pharmacy, in 2006, an American College of Clinical Pharmacy (ACCP) position statement addressing postgraduate pharmacy residency

training for direct patient care positions stated: "formal postgraduate residency training will become mandatory before one can enter practice." Board certification is another area where pharmacists are able to receive additional knowledge following their practical training. In regard to board certification, ACCP stated that it should indicate a pharmacist's degree of mastery, because certification is an index of one's knowledge at a "predefined level that has been rigorously validated."9 Board certification is recognized by the Accreditation Council for Pharmacy Education (ACPE) as an important part of pharmacy faculty.10 Research has also shown that specialization and board certification in pharmacotherapy in pharmacy is substantial and growing. As the number of pharmacists competing for jobs and working within medical affairs is on the rise, the need for more training and education in this specific niche area is important for the profession.

Evolution of Medical Affairs

The way in which medical affairs engages external experts, also referred to as thought leaders or Key Opinion Leaders (KOLs) has shifted as well. Key Opinion Leaders are HCPs typically working at large academic medical centers or involved in professional organizations and they are leaders at a national, state and local level. Traditionally, MSLs were focused on KOLs and served as the primary point of contact. However, there has been a fundamental shift within organizations which are interested in having a 360 degree view of the KOL. This shift is causing several organizations to rethink their KOL engagement plans. Some of this is driven by life cycle planning for a drug. The stage of drug at which medical affairs tends to provide the most support is during registration and launch followed by the first year the drug is on the market.

Pharmaceutical companies increased research and development (R&D) spending by 147% from 1993 to 2004. However, the number of food and drug administration (FDA) drug applications only increased by 38%, a decrease from 1999. By exploring the major trends that have influenced drug revenue growth, one can clearly see that the story begins with the patent expirations that started hitting the industry in 2007, peaked in 2012, and have continued. What is important to note is that the pharmaceutical industry did not have to change until it was forced to think about new ways to bring about innovation at a faster pace. Given the massive loss of revenue from patent expirations – well over $100 billion (B) dollars, the question is how has the pharmaceutical industry responded?

With low returns on R&D investments and drug patents set to expire, companies have invested in late-stage alliances, mergers and acquisitions to supplement their drug pipelines. Although considered less risky, increased competition for fewer target companies has driven the average deal size up by 53% (2003-2005). Traditionally companies reduce risk by forming alliances with late-stage drug developments. However, rising prices have led companies to invest in early and mid-stage developments. By developing stronger relationships with top external scientists, companies promote an ongoing exchange of information and innovation along the entire R&D value chain. Another early and obvious way of driving growth is expansion to new markets. When companies want to grow, they expand geographically. Emerging markets will represent 11% growth from 2015-2018.

Another of the immediate responses to the patent cliff was a significant increase in Mergers & Acquisitions (M&A) activity and this trend continues today. From 1985-2012, the average number of M&A transactions was about 400. In 2013, there was a significant increase in M&A to 1300. There are several reasons for this: M&A helps to diversify or streamline the product portfolio, find synergies and tax savings. At an individual company level companies are going thru M&A to add to pipeline, diversify and streamline their portfolios, extend reach in new markets, and tax savings.

These factors have all contributed to an increased demand for more sophisticated knowledge and education from HCPs. The demand can only be met by individuals who possess the education and training to have in depth discussions with HCPs. However, medical affairs is not limited to MSLs meeting physicians. Most of medical affairs today is 'customer' facing. The stakeholders that medical affairs professionals need to effectively interact with is no longer limited to traditional KOLs but other important stakeholders such as patient advocacy groups, insurers, regulatory KOLs, and other partners such as diagnostic companies which may partner with a pharmaceutical company.

A Universal Standard

It is no secret that medical affairs often deal with very sensitive information related to clinical trials, patient safety, and interactions with HCPs. Having a solid background and understanding across the medical affairs function (not only MSLs) is of paramount importance for both the growth and risk minimization for a company.

The increasing variability in background of medical affairs professionals has created a training challenge for pharma. Traditionally, there have been more PharmDs in the medical affairs space, however, the number of medical doctors (MD) and doctors of philosophy (PhD) are on the rise.16 Eligibility requirements are not similar amongst all certification programs but many industries require basic level of competency. Other industries such as the financial sector, require professionals to become a Chartered Financial Analyst (CFA) and accountants have the Certified Public Accountant (CPA). Often times, there are requirements to either be eligible for or maintain a position. For clinical pharmacists, the Board Certified Pharmacotherapy Specialist program (BCPS) is often a requirement and many colleges of pharmacy require or prefer their faculty members become board certified. Until recently, medical affairs has not had any clear, established standard for the medical affairs professional. With the increasing surge of individuals coming into the medical affairs profession, having a board certification with an examination is critical to determine those that have a higher likelihood of being successful in their roles as well as mitigating risk and liability for the company.

Within the pharmaceutical industry, there has been a tendency to mostly focus on the medical science liaison role only when it comes to training. However, this approach has several limitations. As MSLs grow and evolve in their role, they will transition to other roles within medical affairs. Therefore, being broadly board certified in medical affairs where a board examination is required to demonstrate knowledge raises the bar to distinguish professionals in the field. It also provides a path for development into other facets of medical affairs which is critical for medical and scientific professionals employed in this area.

Recently, in Japan, the Japanese Association of Pharmaceutical Medicine incorporated accreditation standards for MSLs which are now used to serve as a guide for program development across companies. In the US, the Accreditation Council for Medical Affairs (ACMA) has established standards for medical affairs excellence and has accredited a board certification program in medical affairs which includes MSLs.

The Board Certified Medical Affairs Specialist Program (BCMAS) program is an online, self- paced program available to MD, PharmD, and PhD professionals or students who either want to gain employment in the pharmaceutical industry or for current medical affairs professionals looking to demonstrate a higher level of credibility and knowledge within the industry.

As the role of the external medical expert grows in importance, the need to share and collaborate across both academia and industry is critical. The BCMAS board certification program is critical in being able to provide an independent third party to verify the credentials and a minimum level of competency for those who can potentially influence patient safety from a research standpoint. Additionally, the BCMAS program in medical affairs provides access to information that would enhance the overall scientific nature of the external expert relationship and the credibility of the pharmacist within pharmaceutical industry. In addition, it will help ensure that a minimum level of competency is demonstrated and maintained throughout the career of an individual.

The program is the most comprehensive in the industry covering 20 topics spanning everything from medical devices, diagnostics, to health economics outcomes research and clinical trial design. There is a board examination required to achieve the professional designation of BCMAS in the candidate's title. The program is currently utilized by medical, pharmacy and PhD programs for students interested in a pharmaceutical industry career. This is a critical piece as the types of field based teams has evolved. For example, many companies segregate MSLs from HEOR liaisons (also known as outcomes liaisons) and the majority of MSLs have a distinct role from HEOR liaisons.

Summary

Medical affairs as we know it is rapidly changing. New demands for increased technical knowledge and soft skills (communication skills) are pushing the industry to ensure that these professionals are properly trained and prepared for the new era in healthcare. The BCMAS program is an ACCME/ACPE accredited program which provides a comprehensive overview in medical affairs which will help to demonstrate knowledge and competencies over several years. As pharmacists, physicians and PhD scientists consider career opportunities in the pharmaceutical industry, ensuring that they see where the field is going and how to best prepare will be paramount to ensuring both their own success but also enhancing the value medical affairs brings to patients and HCPs alike.

Acknowledgements

ACMA would like to thank the following contributors:

- Suzanne Soliman, Chief Academic Officer, Accreditation Council for Medical Affairs
- Sotirios Stergiopoulos, Senior Vice President, Global Medical Affairs, Ipsen
- Mehul Patel, Medical Director, Allergan
- Tina Kanmaz, Assistant Dean, St. John's University, College of Pharmacy and Health Sciences
- Charles Schmidt, Director, Clinical Program, Santa Casa School of Medicine, Brazil
- Paul Rowe, Vice President, Global Medical Affairs Head of Respiratory, Sanofi