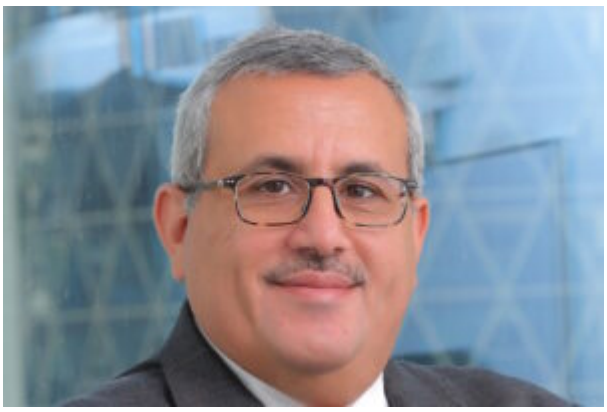
The Evolving Role of Medical Affairs in Pharma: Shaping the Future



25.09.2023

Tags:

Global, Boehringer Ingelheim, Opinion, Medical Affairs, GCC, MEA, META

Mohamed Meshref M.D, PhD is a Professor of Oncology at Cairo University and Regional Medical Director at Boehringer Ingelheim for India, Middle East, Turkey & Africa (IMETA). Here, Prof. Meshref discusses the importance of an 'early medical affairs mindset' within the pharma industry whereby medical affairs personnel engage much earlier in the pre-launch process, thereby driving positive outcomes for companies, healthcare professionals, and – most importantly – patients.

The healthcare landscape is evolving at a speed never seen before. There is an increasing pressure to deliver innovative solutions that improve patient outcomes. In the near future, not only do those solutions need to be tailored to different patients' needs but also to different disease areas and markets.

The role of medical affairs in the pharmaceutical industry has become pivotal and will keep evolving, from establishing much-needed partnerships with a progressive array of stakeholders to becoming the champions of the patient's voice.

A decade ago, the role of medical affairs was to partner with healthcare providers to make sure their patients were getting the best treatment possible. This role is currently changing at a very fast pace. Medical affairs will play an even more significant role in shaping the pharmaceutical industry, bridging the gap between science and patient care.

The future of medical affairs within pharmaceutical companies is bursting with possibilities. By driving real-world evidence; enlarging their outreach to other stakeholders such as investigators, regulators, payers as well as patient advocates; leveraging digital health technologies; fostering cross functional collaboration; and upholding ethical considerations, medical affairs will drive

healthcare innovation forward.

Pharmaceutical companies who have embraced this vision are not only investing in ramping up their medical teams but are focusing on having their medical affairs organization set for the future. This push includes establishing a presence even earlier than the conventional 24 months before launch and adopting a focused approach on the quality of the interactions with stakeholders to answer their needs. This ensures a proper understanding of the patients' needs and treatment pathways, helping payers and regulators to understand the value of innovation for the patients as well as creating advocates even before the prelaunch time.

Therefore, those activities, interactions and understanding of the patients, payers and healthcare providers needs should happen 48 to 24 months before the launch of a molecule in the market, which is the definition of early prelaunch.

For this early prelaunch period, there should be different criteria for the medical affairs personnel that are assigned to those interactions. Their competencies should be different from the regular medical science liaison and should include a strategic mindset, business acumen, communication excellence, patient pathway understanding, market access & HEOR understanding and digital savviness.[1] In addition, project management skills, patient focus, and a full understanding of healthcare compliance is necessary to be able to navigate through this complex environment.

Giving the task of early prelaunch to the conventional medical science liaison who was primarily trained to communicate the science will not achieve what is needed from this period. Therefore, the early medical affairs should be set up with a different mindset from the competencies of people assigned to their onboarding and training.

The early prelaunch period needs to have different plans than the prelaunch strategic brand plan. The early prelaunch plan is built on a foundation of flawless collaboration between medical affairs and internal stakeholders across areas such as clinical operations, market access, regulatory and marketing as well as external stakeholders such as investigators, payers, and patients on top of the regular interaction with the scientific experts.

The basis of the preparation of the early prelaunch plan is dependent on providing a connection between the early medical affairs personnel and the investigators working on the molecule in the clinical trials, the scientific societies working in the therapeutic area, the key opinion leaders, and the patients' advocacy groups. Through this connection, the collection of insights regarding unmet needs, patients' treatment pathways, educational needs, and regulatory authorities and payers' needs will happen 48 to 24 months before launch of any product. This is more prominent when it comes to rare diseases or molecules which could be first in class or first in market.

Those insights will lead to building actions such as disease awareness plans to the healthcare providers and the public, real world data generation and development of digital health technology tools which could help in screening, diagnosis, or adherence to treatment. They can also lead to the development of risk management plans and create a proper dialogue with the regulatory authorities to provider earlier access to the medication. Finally, it can help the negotiation with payers through better explanation of the unmet need and the early preparation of a value dossier which address payers' needs.

Pharmaceutical companies must start relooking at the structure of their medical affairs departments, not only by increasing the number of medical affairs personnel but by enhancing the quality of their plans and interactions, the competencies of the customer facing teams, and most of all adopting an early medical affairs mindset.

References

1- IQVIA Whitepaper, Medical Affairs in a disrupted world, September 2022

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