

Insights into Pharmaceuticals and Medical Products

Is your CMO's role evolving fast enough?

2014

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Is your CMO's role evolving fast enough?

The position of Chief Medical Officer (CMO) is evolving as both the public and the broader medical community look for pharmaceutical companies to apply more ethical and scientific rigor to decision making. Some pharmaceutical companies are investing in a single, global top-level executive who is both credibly independent and capable of meeting two primary objectives: making the voice of the patient heard at the highest levels of the organization and representing the company externally as its primary medical representative.

For leaders to perform this dual role well, however, will require pharmaceutical companies to make fundamental changes to the CMO role as we know it and ensure those changes cascade throughout the organization. Specifically, companies will need to allow the CMO to:

- Have both sufficient independence and authority within the company to affect tough decisions regardless of reporting lines.
- Articulate “the voice of the patient” internally by putting it first in all decisions and evaluating all factors relevant to a patient’s informed decision making, including quality of life.
- Foster a corporate culture of medical and scientific rigor and ethical behavior.
- Represent the ethical and medical voice of the company externally and initiate cross-industry collaboration on medical topics.
- Play a leading role in weighing clinical benefit versus risk, as well as a product’s medical value versus its price.
- Define consistent global standards for medical and scientific activities.

Currently these responsibilities are often split across multiple roles in the organization rather than being shouldered by one senior executive. Some companies, however, have consolidated these activities into a single CMO with the authority to drive change across the organization, especially in times of crisis. This paper traces the role of the CMO and how and why the current healthcare climate requires it to evolve. Although CMO reporting lines and responsibilities will necessarily vary from company to company, we believe that having a single point of accountability for these issues that is independent from commercial activities would benefit both pharmaceutical companies and patients.

History of the Chief Medical Officer

Traditionally, the head of R&D was a pharmaceutical company’s medical voice. Since R&D was responsible for the science behind products, its head was logically viewed as best positioned to continually evaluate the benefits and risks of a product over time. Typically a researcher rather than a clinician, the head of R&D was intimately involved in leading trials that developed scientific data to support product approval by the FDA and other regulatory agencies. With this knowledge of the research behind products, the head of R&D was also best positioned to interpret new data and therapies and decide if product development should be halted or products pulled off the market. Although clearly a strong scientific voice for the

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Over the last decade, increased regulatory scrutiny, poor public perception of the industry, and deep concerns about companies' ability to strike the right balance between product risks and benefits led many companies to create a distinct medical voice (i.e., a Chief Medical Officer role). Often this move was in direct response to specific product safety problems. These pressures also created an external environment in which the medical voice of the company needs both a scientific and a medical background to speak knowledgeably, and independently, from the Commercial and Developmental arms of the organization. In addition, the internal complexity of R&D organizations and commercial activities made it more challenging for the head of R&D to perform both the R&D and CMO roles.

As criticism and pressures grew, the CMO role in many companies evolved to provide a strong medical voice at the highest levels of the organization during critical product discussions. To succeed in the future, CMOs must go further, and have their finger on the pulse of all critical medical activities and decisions while maintaining the independence and authority to act decisively when needed, even against fierce opposition.

Chief Medical Officer models in use today

Given the differences among organizations' structure, processes, talent, and culture, there is not a "one size fits all" solution for the Chief Medical Officer. Yet, companies usually deploy one of three CMO models (Exhibit 1), each of which has strengths and weaknesses that must be managed.

By contrast, CMOs who report directly to the Head of Development typically have fewer organizational responsibilities enabling them to focus solely on typical CMO tasks such as assessing benefit-risk profile, ensuring a high quality clinical program, and leading medical policy. The tradeoff, however, is that separate CMOs may have limited authority within the organization to effect change.

Strong "Medical Officer" roles are used in some companies to distribute the operational burdens of the CMO role. Select medical functions, such as Medical Affairs, Pharmacovigilance, Regulatory Affairs, typically report to these Officers, freeing the CMO of some managerial responsibilities. This can allow the CMO to focus on being the risk/benefit arbiter and provide him or her with the direct reporting lines to quickly drive change in times of crisis.

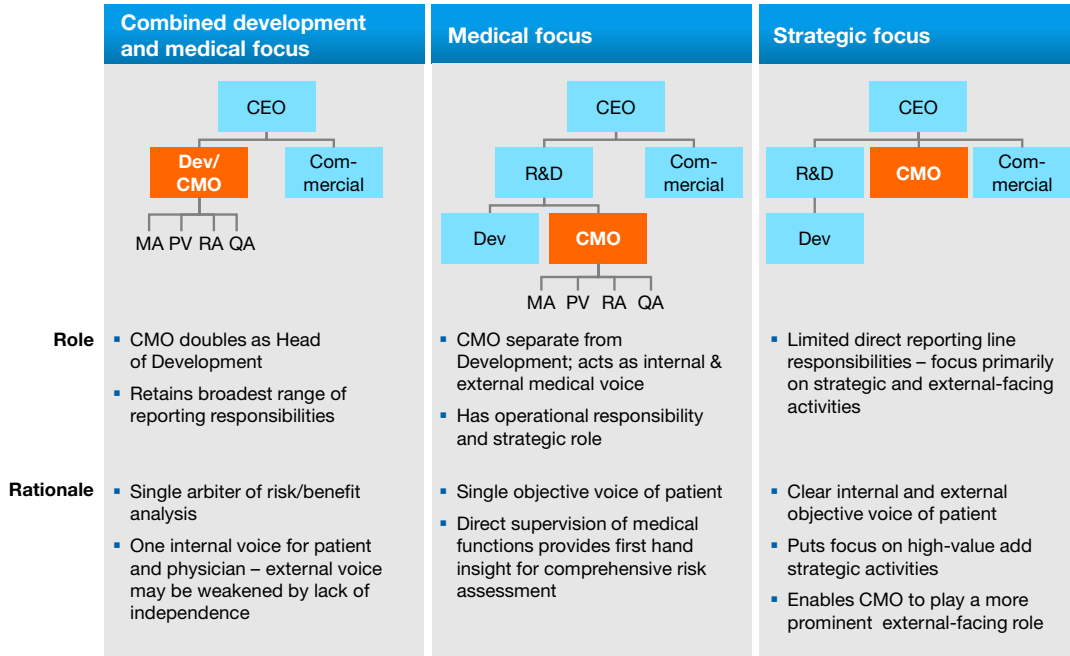
Model 1: Combined Development and Medical focus

In 40 percent of companies, the CMO is closely tied to the Head of Development. Usually, the Head of Development simultaneously bears the duties and responsibilities of CMO or has a deputy with the title of CMO. This model makes a single person accountable for risk/benefit decisions and consolidates all related

activities under this person as well. Direct or closely coordinated reporting relationships from key functions (e.g., Clinical Strategy, Regulatory Affairs, Drug Safety, and Pharmacovigilance) enable the company to act quickly and decisively when needed, and particularly in times of crisis. In this model, the CMO becomes the leading proxy medical voice for the physician and patient within and outside of the company.

Exhibit 1

Three archetypes for the Chief Medical Officer role



When the CMO is also Head of Development, he or she typically reports to the CEO. This structure has the broadest range of operational responsibilities and typically includes medical functions as well as Development when the roles are combined. The advantage of this model is that executives who serve as both Head of Development and CMO have significant credibility, and the breadth of their responsibility can make them key players in critical decisions. At the same time, the sheer breadth of these responsibilities combined with incentives more directly linked to pipeline product management can require time and attention to many operational, non-CMO activities, risking diminished global-local coordination of medical activities. Thus, although these CMOs remain accountable for local medical activities, they often lack sufficient authority or information for adequate governance over local safety and quality.

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Model 2: Medical focus

In another 40 percent of companies, the CMO is separate from the Head of Development, but both typically report to a more senior scientist such as a Chief Scientific Officer (CSO) or Head of R&D. These CMOs are the primary medical voice of the company both internally and externally with the operational responsibility to play that critical role. Reporting lines for relevant medical functions provide these CMOs with both accountability and awareness of local, regional, and global medical activities.

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These CMOs shoulder a broad array of functional responsibilities, typically including Global Medical Affairs, Pharmacovigilance, Quality, and Regulatory Affairs. Direct supervision over multiple medical functions can support the development of a truly global medical organization, independent of commercial and development pressures. In companies that have created effective linkages between global medical functions and local affiliates, the medical organization can provide the CMO with the first-hand insight required to conduct comprehensive risk assessment of products.

A potential downside to this model is confusion regarding the role of the CMO vis-à-vis other senior executives such as the Head of R&D, Chief Scientific Officer, and Head of Development. These CMOs typically report to senior scientists who are not physicians, leading to questions about who the primary medical voice of the company really is, and leaving the executive team without a clear medical lead, which can marginalize the CMO's internal medical voice and influence.

In companies with a strong business unit structure, this model serves as a coordinating hub for medical activities across all of the units. Drug Safety, Regulatory, and Quality are centralized under the CMO, who also develops Medical Affairs strategy and shares sponsorship of investigator-initiated trials, publications,

and medical information. Medical Affairs execution and field medical personnel typically remain within the business units' Medical Affairs teams. This division of labor and responsibility can pose additional challenges for CMOs working to maintain consistent standards and obtain clear visibility into BU activities.

Model 3: Strategic focus

The remaining fifth of companies create a truly independent role for the CMO, a model that carries limited operational responsibilities but has the CMO report to the highest levels of the organization. This arrangement provides the CMO with the time and independence to develop a reliably objective medical point of view for the organization. The strategy-focused CMO model is often adopted following serious safety problems that expose the need for a CMO who combines sophisticated medical knowledge and an external perspective on safety as it affects critical business decisions.

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Strategy-focused CMOs generally have extremely limited direct reporting line responsibilities – typically less than 20-30 individuals focused on project management or other special projects. The lack of direct reporting lines and capacity could also pose a challenge however for these CMOs to participate in critical Development and Commercial committees and wield influence as part of the senior executive team. A seat at the table of such committees is crucial if these CMOs are to learn about potential problems when they first surface and then remain on top of them.



Ideally, these CMOs report either to the CEO or Board of Directors. This not only invests the function with a credibly independent voice, it also provides sufficient standing across the organization to gain inclusion in critical discussions while providing implicit support for difficult decisions on tough issues. Despite the unique challenges posed by the limited reporting lines to a strategy-focused CMO, and the fact that this model was often adopted under some duress, many companies using it are convinced of its advantages.

The future-ready CMO

Although no single model is the “best fit” for all organizations, we expect that all CMO roles will continue to evolve fundamentally. In the future companies will need CMOs that:

- **Have both sufficient independence and authority within the company to impact tough decisions regardless of reporting lines.** Reporting to the CEO or the board provide CMOs with the standing to tackle contentious issues confidently, but those who report to lower levels of the organization should also be empowered to make hard calls or take unpopular stances without repercussions. In all models, CMOs must have clearly articulated authority and visible support from the senior executive team.
- **Can adequately represent “the voice of the patient” internally and evaluate factors relevant to a patient’s informed decision making, including quality of life.** CMOs will need to continue to strengthen their own medical voice within the company, ensuring that critical decisions consider the patient perspective. To do that, CMOs must first consider both how patients make decisions and what they value – including what contributes to their satisfaction with pharmaceutical products. CMOs increasingly must take into account the wide variation in the clinical needs of patients coming from diverse economic, social, and cultural backgrounds across the globe yet many will be challenged to understand healthcare delivery across multiple diseases and geographies. The trend toward sharing of patient-level data will also significantly alter the role of CMOs vis-à-vis patients. CMOs will be the obvious choice to lead how their companies measure the impact of their products on patients. Because they are physicians by training, CMOs naturally provide a doctor’s perspective, so they must make additional efforts to see through patients’ eyes, especially when the two viewpoints clash.
- **Foster an internal culture grounded in both science and ethics.** Senior-level reporting lines to the CEO or board of directors can clearly strengthen the CMO’s influence to make and execute tough calls. But all CMOs must strive to reinforce their influence within the organizational structure so they can lead the organization to respond appropriately and drive change at times of crisis. Most CMOs already serve as the leading internal medical and ethical voice of the company, but they cannot join every committee meeting or discussion at which critical business decisions are made. To contribute to critical medical decisions, CMOs will require appropriate presence on key committees. They will also need to build internal awareness for the CMO role so that they are kept informed of all critical, medically-related decisions facing the organization. Finally, the CMO’s values and judgment must be crystal clear in order to be adopted by and cascaded through the corporation. The cultural goal is to have the entire organization feel a shared responsibility to uphold the same high standards.
- **Be the ethical and medical voice of the company externally.** CMOs have a unique position from which to represent their organizations and provide the industry medical perspective – crucial roles given

the frequent criticisms of pharmaceutical science. With support from the top, the CMO can act as a leading spokesperson both as an individual and in collaboration with other CMOs. This will require making external engagement a priority. Responsibilities and incentives will need to be altered to promote collaboration with payors, providers, and government. While each CMO approaches the challenge of meeting patient needs from different perspectives, changes in healthcare will require greater communication and collaboration among all stakeholders, with the CMO playing a pivotal convening role. Industry organizations with a focus on lobbying or commercial issues will likely not be the most effective channel for CMO influence as these connections can dilute the independence and scientific focus of the role. Cross-industry collaboration with scientific stakeholders will enable collective action to enhance the reputation of the industry as a whole, and move it toward a "right" set of actions.

- **Take a leading role in weighing clinical benefit versus risk.**

The combined Development and Medical model places both risk and benefit under the purview of the CMO as the Head of R&D. The other models move the CMO role out of Development and focus the CMO on risk evaluation. This responsibility is most important when the safety of a product is at issue, yet this evaluation is also becoming more complex. In the future, CMOs will need to decide whether products deliver an adequate balance of benefit-risk value not only in comparison to placebos or a lack of treatment, but also compared to all other available treatment options in a market. As pharmaceutical companies expand beyond the delivery of products to delivery of related services, such as adherence and patient access programs, CMOs will play an important role in evaluating whether these services meet the needs of patients and how the value of these combined products and services impacts the benefit/risk equation.

- **Weigh a product's medical value versus its price:**

As product value becomes more critical to patients, payors and other medical decision makers, CMOs will also participate in decisions on whether a product is delivering value. Product pricing will, of course, remain under the purview of Commercial functions, but as cost becomes a more significant driver of medical decisions, CMOs will not be able to evaluate products as if they were free. CMOs will need greater exposure to and deeper skills related to assessing the value side of the equation to be able to participate fully in the wider scope of product evaluations.

- **Define consistent global standards for medical and scientific activities.** Compliance standards in the traditional markets of the U.S. and Europe are tightening, driving significant changes in behaviors as

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the scope and execution of medical activities within these countries adjust to the new standards. With compliance regulations in emerging markets largely lagging behind those of the developed world, companies leave themselves open to significant risk by following different sets of standards across the globe. Companies are increasingly turning to their CMOs to define both risk tolerance and the global standards needed to keep internal medical activities in line with this risk level.

A true expansion of the Chief Medical Officer role would create significant value for individual companies and the pharmaceutical industry as well, but will also require significant change to unleash that potential. These changes range from CMOs' willingness to upgrade their own skills and aspirations for the role, and companies' ability to move proactively to develop the next generation of CMOs. Regardless of how the role evolves, or how quickly, the central motivating factor for CMOs will remain the improvement of patient care and outcomes.





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