Corporate Affairs in the Pharmaceutical Industry: How to Succeed in a Complex and Evolving Landscape

By the year 2030, global pharmaceutical demand is expected to grow more than 6% with expenditures approaching USD$1.5 trillion. Layered above this growth are complexities including new modalities, the increased reliance on artificial intelligence (AI) for drug discovery and development, improved manufacturing efficiency, more efficient and reliable supply chains and changing policies on product pricing, access and corporate governance, coupled with the requirements associated with reporting on environmental, social and governance (ESG) and diversity, equity and inclusion (DEI).

Corporate affairs leaders at the helm of pharmaceutical brands face a challenging task: connect a myriad of factors that are constantly changing and impacting the business differently over time, while also maintaining the confidence of investors, partners and other stakeholders. Through corporate affairs, the business seeks to build and protect reputation, cultivate trust, build an efficient, accurate and robust information conduit that may be relied upon by employees and business leaders alike and perform the daily work of corporate communications.

Implications for Corporate Affairs and Communicators

Corporate affairs functions in pharmaceutical companies must deal with geopolitical issues such as an overreliance on China for active pharmaceutical ingredients, increased dependency on countries such as India for generic drug production, supply chain vulnerabilities and regulatory shifts in the EU, UK, United States and worldwide. The industry itself must adapt to changes in drug development and production driven by AI and pricing challenges in virtually every country.

This new landscape resembles a multidimensional chess board that demands new skills, partners, information and a nuanced outlook. This paper seeks to define the factors that global pharmaceutical corporate affairs will face in this rapidly changing business, technology and regulatory landscape. Understanding these factors are essential to building a dynamic corporate affairs function for the rapidly evolving dynamic that the industry faces (see additional background on global factors).

At the heart of the evolving ecosystem are six formative factors: supply chain vulnerability, overreliance on China and India, regulatory issues, pricing and access issues, the adoption of AI to many company functions and public health and equity issues. This is the complex, matrixed environment within which today's pharmaceutical communicator must navigate:

Geopolitical:
The impact of India and China

India is the largest producer of generic medications and is a rapidly growing market for the production and sales of pharmaceuticals. China has become the primary source of active pharmaceutical ingredients. From discovery to production, these two geographies have become essential to the pharmaceutical trade—from production to sales. This ownership of the means of production impacts the supply chain and potentially creates vulunerabilities.

Technological:
Use of AI from discovery and development to production

AI is both upending and advancing the pharmaceutical business. The drug discovery process is accelerating with new AI-driven processes increasing the speed at which new molecules are discovered. Likewise, the technology is changing how the supply chain functions by automating processes and improving reliability. Within the enterprise more functions are relying on AI and seeking to protect the business against threatening cyberattacks.

Policy:
Country-driven efforts to address pricing and cost

Between the impact of the Inflation Reduction Act in the United States and the proposed regulatory changes for the EU, countries and nation states are changing the pharmaceutical ecosystem by focusing, pricing, and purchasing to affordability and access. The potential changes are wide-ranging and impact how business is conducted at each point of the pharmaceutical spectrum—from production to providers and patients.

Supply Chain:
Efficiencies and opportunities to strengthen the chain

Global pharmaceutical companies depend on long, often complex supply chains to produce and distribute approved drugs worldwide. The growing number of shortages linked to supply chain issues, climate threats, the health and resilience of supply chains impacts accessibility.

Public Health, Equity and social determinants of health (SDOH):
Accessibility hinges on it

Global pharmaceutical companies, like devicemakers, hospital systems, providers, and payers, are accountable for reducing health disparities, building health equity and advancing the social determinants of health are critical and in doing so, improving health outcomes.

Regulatory Issues:
Increasing scrutiny of healthcare businesses including pharmaceutical companies

Countries, nation states and political and economic unions are seeking to make it easier and fairer to approve and sell medicines to improve the health and wellbeing of more people globally. With these changes come new regulations and changes in how business is done. These factors influence business growth and innovation.

Change Drivers and Response Factors

There are opportunities and challenges from a corporate affairs perspective for each of the change drivers noted above. To equip and enable leaders and communicators to respond and engage appropriately APCO recommends building…

1. **A resilient team:** Dynamic change demands a skilled and responsive team with a deep understanding of the many challenges facing the business. Team members must be capable of collaborating with internal experts and external stakeholders while defining firm boundaries to ensure communications do not become a catchall for crisis management. Communicators must, on a global basis, anticipate change and unpredictable challenges, bring together stakeholders, listen with empathy and work together.

2. **A definition for effectiveness:** The multitude of linked factors require corporate affairs leaders to identify connections across the issues and develop and deliver messages across the corporate narrative. A strong, contextual narrative helps key audiences understand the myriad of regulatory, economic, investor/employee and climate/sustainability pressures that face companies and the industry more generally.

3. **Real-time insights:** Sometimes, change is not obvious. It grows and slows at paces and frequencies we don't always recognize. Effective corporate affairs functions must monitor for change and the surrounding noise. Creating a system that tracks issues, people and policies helps communicators see and interpret the changing landscape and determine how best and when to respond.

4. **Relationships, everywhere:** As pharmaceutical companies adapt to this evolving environment, relationships become more essential. A resilient communications program recognizes the importance of developing and maintaining strong relationships that support the needs of the business and its ecosystem.

5. **Thought leadership:** While the issues are unfolding and change becomes the new norm, there are opportunities to highlight the value that global corporate affairs contribute by amplifying and seizing opportunities for thought leadership. From LinkedIn to an op-ed or a speech, these opportunities allow corporate affairs to flex and highlight how the company is bending, shaping and responding to change and challenges.

Interested In learning more? APCO helps the world's leading pharmaceutical companies navigate complexity and drive value to the business for upwards of 40 years. More information about capacity building for communicators within a changing pharmaceutical is available.

Background About the Change Drivers

Overreliance on China and India: For the U.S. pharmaceutical industry, business growth and innovation depend on advancing the pipeline either through new drug development, partnership or acquisition. Considerable drug discovery, including AI-driven efforts and manufacturing, is being done abroad in China and India. China has become the major source of active pharmaceutical ingredients, while India's generic drug manufacturing capability continues to grow. The U.S. pharmaceutical industry and health care system are dependent on China and India. The substantial number of drug shortages in the United States illustrates this vulnerability.

A central issue facing the industry is reconciling the need for business growth without ceding the innovation to non-U.S. countries' partners. Relying on non-U.S. sources for essential functions places the United States in a vulnerable position.

There are emerging legislative efforts focused on onshoring innovation. In the United States, the issue has bipartisan appeal.

The U.S. BIOSECURE Act aims to protect American genetic data and personal health information from foreign adversaries. When the Act made its way to the Senate floor, BIO, the industry trade association, changed its position from advocate to opponent in part because of strong sentiment about protecting United States advantages in the biotech sector. The Act seeks to address concerns around biotech competition with China by prohibiting executive agencies from contracting with or extending loans or grants to any company with current or future commercial arrangements with a biotechnology company of concern.

The BIOSECURE Act emerged following several U.S. government-focused actions on China's biotech sector and efforts to de-risk the U.S. biotech industry. In 2022, the White House issued an executive order to strengthen the resilience of the domestic biotech supply chain. Congress charged the National Security Commission on Emerging Biotechnology with reviewing the critical intersection of emerging biotechnology and national security. A similar provision that prohibits the Department of Defense from entering contracts with these companies was passed as part of the National Defense Authorization Act for the 2024 Fiscal Year.

The Act represents steps by the federal government and the private sector to reduce or block Chinese investments in pharmaceutical research and drug development. The NIH and CDC banned funding for Wuhan lab research in China. In addition to defensive moves, initiative-taking efforts are also underway. Deerfield Management, an investment firm, announced in 2023 a $25 million grant from New York State and Empire State Development to build a lab with the goal of reversing an increase in drug discovery and development outsourcing—primarily to China and India.

Supply Chain Vulnerability: Another vulnerability for the pharmaceutical industry relates to the supply chain. The pandemic laid bare the vulnerabilities that global supply chains face and the impact that obstacles have on product availability and patient care throughout the healthcare continuum. But the problem remains.

McKinsey **research found that in the past two decades,** the value of pharmaceutical goods traded grew from $113 billion in 2000 to $629 billion in 2019. The growth has caused constant challenges and risks for company supply chains. One complicating factor—outsourcing—has the potential to create chains so complex that they circumnavigate the globe twice.

Cyberattacks, trade concerns, geopolitical issues and natural disasters have the risk of disrupting supply chains still further. For example, Pfizer faced severe shortages of its injectable supplies after climate events, including a hurricane. McKinsey Global Institute estimates that the pharmaceutical industry is at risk of losing an average of 24 percent of one year's earnings as global events and crises become more commonplace.

Coupled with supply chain vulnerabilities, the state of manufacturing also threatens the health of the U.S. pharmaceutical industry. The Senate Committee on Homeland Security and Governmental Affairs report details

the dire state of biomanufacturing. At the end of 2022, drug shortages saw a record five-year high of 295 active drug shortages. The biopharmaceutical manufacturing industry is looking to more effectively apply computational technologies and automation to improve processes and shorten timelines. This happens as a pipeline of molecules and compounds stemming from AI drug discovery is expanding rapidly. In May 2023, the FDA predicted an increase in the number of drug and biologic application submissions using AI/ML components, which were already greater than 100 in 2021.

Consolidation of EU Regulation: One additional challenge facing the industry is how to ensure that regulatory agencies keep up with the changes. FDA has always sought to keep up with the rapid change and has committed to seeking innovations in how new drugs are developed, assessed and reviewed. In the European Union, there is a mandate to streamline the innovation and regulatory processes.

The EU has attempted to reduce fragmentation by creating a Joint Clinical Assessment (JCA) for HTA that will require evidence to be submitted only once at the EU level from 2025. It is hoped that by avoiding multiple country-specific assessments, the EU will improve the functioning and transparency of a single market.

Building on the JCA's efforts, the European Commission's revisions of EU pharmaceutical legislation represent a focus on streamlining the market for medicines, creating incentives for companies to meet public health objectives and improving access, conducting clinical trials and developing diverse medications. There is also a focus on increasing the availability of more affordable therapeutics in the form of generics and biosimilars.

AI analysis shows that these revisions will be the first major review of the EU pharmaceutical legislation since 2004. The UK has enacted a new procedure that will allow medicinal products approved in other countries that meet certain criteria to undergo a fast-tracked review to obtain and/or update a marketing authorization.

The Commission's efforts to revise the EU pharmaceutical legislation align with U.S. efforts to reign in pharmaceutical drug spending and reduce the federal deficit over time with the Inflation Reduction Act The regulation is expected to potentially reduce access to Medicare Part B and Part D-covered drugs. Pharmaceutical companies are anticipating a business impact, with studies showing that by 2039, IRA requirements could result in a significant impact on industry income.