Nine for 2023, part one: a reflection on inflection

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The Roman god Janus, as we are frequently reminded in January, was two faced and able to look forward to the coming year and backward to reflect on the past one. Forecasters use terms like “unprecedented,” “inflection point,” and “transformative” when in forward-facing Janus mode. What’s often forgotten is the backwards-facing, reflective mode: when we predicted unprecedented challenge in the past, did it really happen?

This Nine for 2023 three-part series will argue that, this year, the future-facing Janus prediction of unprecedented and transformative change is true. In some ways, it is not difficult to understand why: healthcare faced unprecedented challenge from the COVID-19 pandemic and responded in an extraordinary way. However, the pandemic is only one of the often deep-rooted forces that will come together in 2023 to exert transformative pressure on healthcare.

This article is the first part of three and covers the first three of nine predictions, here focusing on global healthcare environmental challenges and what they mean for the pharmaceutical industry.

1. Things fall apart: deglobalisation

The pandemic was a wake-up call for many countries on the risks of a globalised medicines supply chain. In the early stages, the location of Active Pharmaceutical

Ingredient manufacturing in China and then subsequent generic manufacture in India generated significant concerns as these countries were met with major COVID waves – however, for the major markets of Europe and US, the impact on generic supply was in fact low and early talk of deglobalising and relocalising manufacturing subsided. Deglobalisation has, however, not gone away and 2023 will see acceleration of this trend, manifested in the following:

- Lower- and middle-income countries (LMICs) were exposed to medicine supply issues because of the pandemic, as they lacked both funds to secure supply and their own manufacturing capacity. Africa, as a continent which imports up to 90% of its medicine needs, was especially exposed. This has triggered change, as discussed in IQVIA's November Africa Health Summit.[1] Kenya, for example, entered the pandemic with no human vaccines manufacturing facility and established the BioVax institute for local vaccine manufacture with a major plant investment starting in 2023. Localised manufacturing could gain momentum in LMICs in 2023, as they seek to improve supply resilience.
- Higher income countries will also pursue plans to localise in 2023: Germany wants statutory health insurers to consider local production for drugs in tenders to prefer reliable European manufacturers, and the EU medicines strategy in March 2023 will ensure a future-proof and resilient system, reducing the EU's dependency on third party countries.
- Regulatory divergence became apparent in 2022 and could increase in 2023. Despite positive convergence steps such as Project Orbis to harmonise the approval of cancer treatments across regulators, there are significant fault lines. China still hasn't approved western mRNA vaccines, despite submission, and the US FDA rejects Chinese-only trial data for cancer medicines. The battle between harmonisation and fragmentation is often finely balanced, but at present, it seems to be tipping more to fragmentation.

The presumption that an increasingly globalised pharmaceutical industry is inevitable will be tested in 2023. The consequences of the US pricing and profitability situation could drive some companies to make portfolio investment decisions based on the US situation alone. In the near term, profitability-wise, it may make sense, but it is also investing in medicines for just 4% of the world's population. In the longer term, that won't be sustainable.

2. Things fall apart: healthcare system stress

2023 is the year when the longer-term impacts of the pandemic will combine with economic crises to test healthcare systems as they have never been tested before. Regardless of country wealth, the challenge of backlogs and increased demand due to COVID and other infectious disease waves, the complications of COVID and under-treated conditions triggered by lockdowns, as well as understaffing due to resignation and burnout, currently outpace any potential funding increases and technological innovations' capacity to address.

The pandemic did not break healthcare systems: it simply exposed and accelerated the stresses that had been building for years, driven by ageing populations, increasing morbidity, and lack of comprehensive reform. For pharma, the impact in critical areas such as the performance of newly marketed innovation has already been documented. Stretched health systems have less time and money to adopt new products, except in exceptional circumstances, such as first ever treatments for serious conditions.

Pharma needs a new mindset for this “permacrisis” in healthcare – one where the broader needs of the healthcare system are a key consideration in the development and introduction of innovation. Pharma is on a journey in which the core consideration was once the prescriber, now patient needs are more commonly considered as central. That should remain, but patients cannot get treatments unless the needs of the over-stretched health systems in which they will receive care are also met. For example, medicines which can save healthcare professionals time as well as money, treatments that can be given outside of stretched hospital facilities, companies which provide a patient support service as well as a product. Pharma’s starting to wake up to this. Some of the more resilient launches since 2020 have had these benefits to health systems. More remains to be addressed, and not just by conventional pharmaceutical companies. Technology’s real healthcare moment is likely to be providing solutions which support creaking health systems, but the pace must accelerate.

3. Pharma boxed in? Strategic choice challenges for 2023

The innovative prescription medicine industry faces a trifecta of challenges. While the challenges are common, the strategic choices to address are tricky and highly individual. The triple challenge can be divided into long term, near term, and future, all with the same ultimate impact: profit erodes and return on research and development investment reduces.

Over multiple decades, the value movement from primary care to specialty products brought other changes. Compared to major primary care markets of the late 1990s/early 2000s, specialty care markets see more and earlier competitive launches, and the market share achieved by each launch after is progressively reduced. For key 1990s-2000s therapy areas, mostly top selling primary care - such as proton pump inhibitors, statins, and angiotensin II antagonists – had a launch every three years. Now, for major specialty care therapy areas, including Hepatis C, Immuno-oncology and HIV, there is a competitive launch nearly every year. This has a direct impact: in the primary care era, the first five products to market could expect a global share of that therapy area’s value of 10% or more; now, only the first three launches can, and the drop off from first to market to followers is precipitous. Research and development spend by major companies has increased 44% since 2016.[2] Selling, general, and administrative expense for the same large pharma cohort has declined slightly as a percentage of sales, but in absolute terms it has risen.

The long-term return on investment challenge is now compounded: since 2020, excepting COVID vaccines and therapeutics, innovative launches are performing worse on average than their pre-2020 counterparts. In fact, first six months sales are almost 20% lower. This reduction persists, as the earliest 2020 launches still underperformed pre-pandemic launches at an equivalent time point in 2022. This worrying trend is driven by patient journeys and treatment backlogs, reducing patients available for launches, the interactive engagement time pharmaceutical reps spend with doctors, and budgets for new medicines tightening.

All these pressures will persist in 2023, but budgetary challenge will accelerate, becoming the dominant theme for the rest of the decade. The Inflation Reduction Act (IRA), passed in the US in 2022, promises profound changes to US prescription medicine funding, which could have consequences for what large pharma chooses to develop and launch globally, as the US represents 60% or more of the typical innovative launch’s first five years cumulative global sales. It is not alone. All major European countries and Japan are in the process of controlling or planning significant measures to control budgets, manage prices, or manage the introduction of new medicines. China is no panacea for innovation. Strict measures require substantial discounts for new medicines to be covered on the National Reimbursement Drugs List, just as volume-based procurement decimates the value from older medicines.

Classic strategy analysis might suggest three options to address the return-on-investment challenge: reduce costs, enter new geographies, or change portfolio. In reality, the first two options have very limited potential. R&D costs are pharma’s “Red Queen” challenge – constantly rising because of competitive, technological, and healthcare system pressures. Other costs, while managed, can neither be eliminated nor reduced to the point they move the needle substantively on ROI. On geographic options, the numbers are stark: the eight leading country markets account for 90%+ of the first five years of innovative medicine sales, and no single country outside that top eight is greater than 4% of global pharmaceutical market spend. This will not change soon.

While pharma should continue to explore cost and geography wherever possible, the only mid-term strategy with substantive potential is portfolio change – whether within the existing prescription medicine envelope or outside in adjacencies. The 2023 portfolio choices, including M&A, of large pharma therefore have special resonance. The pause button was on for major acquisitions throughout 2021 and for most of 2022. This must change in 2023 if companies want to affect the level and speed of portfolio transformation they will need.

The next article in this three-part series will explore three of the areas of growth and opportunity for innovative healthcare companies.

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