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Making Medicine A Team Sport To Deliver Better Results For More Patients

by Hettie Stroebel

The global pharmaceutical industry has had many innovative successes and now faces an equal amount of challenges to bring more medicines to patients around the world. The disparate parts of the healthcare system must work together to ensure patients have access to therapies.

The global pharma industry today is immense, exceptionally complex, heavily regulated, and drug discovery and development takes years and is significantly expensive. The global market is expected to grow from \$1454.66bn in 2021 to \$2135.18bn in <u>2026</u>.

Increasingly, around 2624 emerging biopharma companies (those with less than \$500m in annual sales and less than \$200m per year on R&D spending), are currently developing nearly 4,000 drugs, and involved in 72% of the current drug development pipeline.

The health care industry continues to be high on the interest list of investors. Venture capital deal activity and investment flows in the US accelerated in the past two years with more than 2,000 deals and \$47bn of deal value occurring in 2021. The 15 largest pharmaceutical companies invested a record \$133bn in 2021 in R&D expenditure, an increase of 44% since <u>2016</u>.

Based on a sample of 311 biopharma acquisitions from 2005 to 2020, companies developing orphan, multi-indication, and oncology drugs were valued significantly higher than their peers during later development stages. Significantly higher returns for shareholders of companies with orphan relative to non-orphan-designated lead drugs from Phase I to FDA approval (46% vs. 12%). Drugs developed across multiple indications also provided higher returns than single-indication agents from preclinical to FDA approval (21% vs. 11%). Returns for oncology drugs exceeded other disease *areas* (26% vs. 8%).

More importantly than all other achievements, a total of 329 novel active substances (NAS) were launched in 2021, with oncology, neurology and infectious diseases all having a rising share of



global launches. In 2019, 42% of the drugs approved by the FDA were indicated for rare diseases. A total of 76 orphan drug-designated products were approved by the FDA for the first time between January 2016 and January 2020.

Despite the strong showing in ROI, global drug launches, and regulatory progress, the pharmaceutical industry needs to do more for patients collectively. The surgeon, Atul Gawande, author of several best-selling books, said in his 2017 TED Talk: "Medicine Has Become a Team Sport — So How Do We Treat It Like One?"

Implement R&D Priorities To Achieve The Vision For 2030

The United Nations has called for a decade of action to achieve its Sustainable Development Goals (SDGs) and universal health coverage (UHC) by 2030. To achieve the SDGs and UHC by 2030 despite the impact of COVID-19, the pharmaceutical industry must complete a shift in how it addresses access to medicine.

The Access to Medicine Index assesses 20 of the world's largest R&D-based pharmaceutical companies on their actions to improve access to medicine for people living in the low- and middle-income countries measured by the Index, which are home to more than 83% of the global population.

The 20 companies in scope account for more than half of global pharmaceutical revenue. Considering their pipelines, portfolios, resources and global reach, these companies have a unique capacity to develop the health products that people in LMICs need, and to improve the availability of these products across socioeconomic divides.

The 2021 Access to Medicine Index results show progress in how companies are integrating access to medicine into governance structures, R&D processes, and monitoring efforts.

The report showed that <u>GlaxoSmithKline Pharmaceuticals Ltd.</u> retains the top position, yet only slightly ahead of <u>Novartis AG</u>. The leaders are followed by <u>Johnson & Johnson</u>, <u>Pfizer Inc.</u>, and <u>Sanofi</u>. GSK's performance in R&D is a significant factor in its retention of the top spot. It has access plans covering the largest proportion of late-stage projects (20/25). Novartis closes in on the number one position through its performance in product delivery and stands out for being the only company to apply equitable access strategies in at least one low-income country for all products assessed. Near the bottom of the ranking, <u>Astellas Pharma, Inc.</u>, <u>AbbVie Inc.</u> and <u>Daiichi Sankyo Co., Ltd.</u> are the only companies that do not have an access-to-medicine strategy with a business rationale. <u>Bristol Myers Squibb Company</u> takes the bottom rank with limited evidence of access initiatives across the areas measured.

Establish Collaborative Business Models



The Covid-19 pandemic has exposed where the biggest fault lines are in global access to medicine, and how much more must be done to fix them. More widely, the pandemic has created a greater awareness of unequal access to healthcare and health products faced by people all over the world.

In so many ways, the corporate, public, and private sectors have stepped up since the pandemic began, developing new vaccines at unprecedented speeds while also tackling severe strains to public health services.

The COVID-19 pandemic has provided a case study for the role played by the pharmaceutical industry in developing and delivering health products and exposed the vast and complex network of supply chains and logistics that factories, clinics, and pharmacies depend upon.

Institute New Regulatory Incentives For Drug Discovery And Development

Consideration needs to be given whether the key regulatory bodies should initiate another set of incentives to boost the development of innovations to improve mortality outcomes in the top 10 diseases with the most deaths (see box)

Oncology and rare diseases dominate the industry pipeline, fueled by regulatory tailwinds and high prices. But as the world grapples with coronavirus, and with heart diseases still the top killer, how can our systems fund treatments for more prevalent and burdening diseases?

Co-Develop Solutions With Payer Decision Makers

It is essential to note that drug discovery and development today incorporates drugs for high-prevalence chronic progressive diseases, rare diseases, and advanced therapy medicinal products (ATMPs): gene therapies, somatic-cell therapies and tissue engineered therapies.

Dimensions Of Disease And Prescription Rates

According to the World Health Organization, the leading cause of death globally are:

- 1. Ischaemic heart disease
- 2. Stroke
- 3. Chronic obstructive pulmonary disease
- 4. Lower respiratory infections
- 5. Neonatal conditions
- 6. Trachea, bronchus, lung cancers
- 7. Alzheimer's disease and other dementia
- 8. Diarrhoeal diseases



A one-size-fits-all approach is not suitable nor implementable for all therapies. Product costs for a chronic treatment can be spread over the full duration of treatment. After patent expiry, with the introduction of generics, prices are drastically decreased, resulting in savings to the healthcare system for the chronic product. The growing number of drugs approved for orphan diseases, in aggregate impacts budgets dramatically due to higher prices.

Greater co-development of solutions between industry, policymakers, and payers are needed to ensure that as many patients benefit from drugs to improve their health. Clearly, success is measured by what we accomplish together for more patients.

Hettie Stroebel is founder and CEO of Launch Excellence Partners with more than 30 years of life sciences experience. Stroebel is a former Merck & Co., executive who ran business units ranging from \$100m to \$1bn per year and led seven product launches, all exceeding profitability targets in major global markets.

- 9. Diabetes mellitus
- 10. Kidney diseases

The most prescribed medicines worldwide are:

- 1. hydrocodone
- 2. metformin
- 3. losartan
- 4. antibiotics
- 5. albuterol
- 6. antihistamines
- 7. gabapentin
- 8. omeprazole
- 9. levothyroxine
- 10. atorvastatin