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Pandemic Perspectives: COVID-19 Upended Drug Launches In Ways That Will Stick

Hybrid Commercial Models Are Here To Stay

by Jessica Merrill

Preliminary data from IQVIA suggest 2020 was one of the weakest in recent years for new launch trajectories although drug companies tell *Scrip* there are some lessons learned from promoting during the pandemic.

Drug makers quickly pivoted to virtual and hybrid drug launches in 2020 as physicians recalibrated how they operate amid the COVID-19 pandemic and as sales reps and patients largely kept away from doctor's offices. Preliminary data from IQVIA suggest COVID-19 significantly impacted the trajectories of the drugs that launched last year, and many of the headwinds are expected to continue throughout 2021 as well.

Pandemic Perspectives

One year on from the World Health Organization declaring COVID-19 a global pandemic on 11 March 2020, editors across Informa Pharma Intelligence publications are taking a *closer look* at its impact and possible lasting implications for the biopharma and medtech industries.

"Launches in 2021, unfortunately from a launch environment perspective, face a pretty tough environment because many of the factors that caused 2020 to be super tough for some launches continue into 2021," IQVIA's Sarah Rickwood, VP of European marketing and thought leadership, said in an interview.

"Pharmaceutical companies will have to learn to adapt their launch plans to address those challenges, as they did in 2020, but probably in a more fundamental and strategic way this time," she added.

In 2020, US launches were among the weakest since at least 2015, ranking closely only with 2018, according to IQVIA, based on two different metrics: time-aligned average monthly sales by year of launch and time-aligned average total prescription units by year of launch. IQVIA cautioned that the data are early and only include drugs that launched in the first six months of 2020; the full outlook will continue to be monitored.

In four of the five major European countries (UK, Germany, France and Italy, excepting Spain), 2020 was either the worst year for launch sales uptake in the first six months since 2015 or the second worst, IQVIA said.

The impact on new drug launches isn't surprising given that many patients skipped doctor visits, particularly in the early days of the pandemic during the first half of 2020, when the virus' trajectory remained highly uncertain. Drug companies also curbed face-to-face visits by their sales reps to doctor's offices out of concerns about doctors' time constraints and safety. Missed doctor visits correlate with missed prescriptions, especially when it comes to new prescriptions or switches to new drugs.

IQVIA forecasts that 111 million US prescriptions, or 3.8% of total US prescriptions, will be lost through the first half of 2021 due to missed diagnosis visits. Their data suggest there were over 1 billion diagnosis visits that didn't happen in the US in 2020, with oncology, gastroenterology and dermatology being the most heavily impacted therapeutic categories. Those trends are expected to continue, with IQVIA forecasting diagnosis visits to be down 8.8% in the US in the first half of 2021 versus a pre-COVID baseline.

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Despite the headwinds in 2020, some launches did stand out, most notably *Horizon Therapeutics plc*'s Tepezza (teprotumumab), which launched in February for the serious rare condition thyroid eye disease (TED). (Also see "*Horizon Heralds Stellar Launch Of TED Drug Tepezza*" - Scrip, 6 Aug, 2020.) The drug is on track to be a fast blockbuster, generating $820m in 2020, though it has been hung up by a supply constraint because its third-party manufacturer, Catalent, has been directed to ramp up vaccine production by the US government. (Also see "*J.P. Morgan Extras: Pandemic Impact on Launch, Production, Development And More*" - Scrip, 18 Jan, 2021.)

Tepezza accounted for a significant amount of revenue from new drug launches in the US last

year. Data from Datamonitor Healthcare show Tepezza made up 47% of the total $1.74bn in revenue generated from new drug launches in the US last year, excluding drugs for COVID-19. *Gilead Sciences, Inc.*'s Veklury (remdesivir) for hospitalized COVID-19 was a big commercial winner in 2020, generating $2.8bn, but the future growth trajectory for the product remains uncertain.

Pandemic Pivoting

"The virtual and hybrid model is definitely not the ideal way to launch a medicine," Horizon CEO Tim Walbert said in a recent interview. The pandemic hit the US just as Horizon was ramping up for the launch of Tepezza, and ophthalmologist offices were shutting down – there was a roughly 70% decline in the number of offices open.

Walbert attributed most of the drug's early commercial success to the strong efficacy data supporting the approval in a debilitating disease which had a bolus of patients awaiting treatment, but he also credited the company for making adjustments to the launch plan.

"We took two immediate actions which we felt really did make a difference," he said. The company pivoted from planned infusions in the hospital setting to alternative sites of care, including identifying more than 1,000 alternative sites for administering infusions, anticipating that hospitals could be overrun caring for COVID-19. Horizon also accelerated its planned direct-to-consumer advertising plan to reach out to patients.

"Because of physicians' offices being closed, we needed to get directly to patients to help them understand the symptoms of the disease and that they should see a specialist who understands thyroid eye disease," he said.

IQVIA's Rickwood pointed to Tepezza as being an exceptional launch in a challenging year. "It does share one characteristic with other launches that also exceeded expectations, though not necessarily as spectacularly as Tepezza did, which is that it's an orphan medicine," she said. "We saw orphan medicines were among the launches that outperformed expectations."

Lessons Learned

As the pandemic has stretched beyond one year, drug makers have gained more experience with hybrid commercial models where sales reps interact with physicians virtually when appropriate and hold face-to-face meetings when permitted and necessary. The amount of face-to-face engagement in the US is still well below pre-pandemic levels, however, at about 39% of what it was at baseline as of February across specialties, according to IQVIA. In some therapeutic areas it remains lower.

Specialties like cardiology, gastroenterology and dermatology have returned to near 50% in-person detailing, while psychiatry, primary care, rheumatology and oncology remain below 40%.

Oncology remains the lowest with just 20% of sales details being in person versus pre-pandemic levels.

Telehealth visits for patients have not been productive for new prescriptions in many therapeutic categories, particularly in dermatology and primary care, even as the length of the pandemic has been prolonged, according to IQVIA. That's because patient mix for telehealth visits frequently skews towards existing patients and lack of diagnostics, such as vitals and labs, impedes diagnosis of new conditions.

GlaxoSmithKline plc senior VP-US oncology Mike Petroutsas said the company's face-to-face interactions are at about the industry standard at the moment in oncology, a therapeutic area the company only reentered in 2019 with the acquisition of Zejula (niraparib) from Tesaro and doubled down on in August 2020 with the launch of Blenrep (belantamab mafodotin-blmf) for relapsed/refractory multiple myeloma. (Also see "*GSK's Blenrep Wins BCMA Race, Carries Ocular Toxicity Warning*" - Scrip, 6 Aug, 2020.)

"What we find is that there is a little fatigue from the physician point of view," Petroutsas said of the prolonged virtual environment. "But there is also a lot of concern because in oncology most of our patients are immuno-compromised. They want to strike the right balance, so we see it as a hybrid type of approach."

As the company prepared to launch a new indication for Zejula early in 2020, followed by Blenrep midyear, Petroutsas said the company quickly focused on accelerating GSK's telehealth capabilities for physician interactions and digital capabilities for patient services.

"There is a lot of work required around changing the content to make sure it fits the channel. What you can do live is a little bit different than what you need to position digitally, making sure that it is small, snap-able, consumable," Petroutsas said. "That sounds easy but again, in a highly regulated environment like ours, where you require a stringent approval process, we really needed to make sure that we sat down and really prioritized what those resources would be for our patients."

GSK also invested in training its commercial team to communicate in virtual formats. "We are used to doing it live, reading signals, reading physicians and patients and understanding," he said. "We really early on realized that it's different when you do it virtually. We invested time in our scientific and commercial engagements and coaching and helping people understand how to engage with someone, how to keep a dialogue going and how to present clinically relevant information in a virtual manner."

MorphoSys AG, a small European biotech, was in the interesting position of launching its first commercial product in 2020, Monjuvi (tafasitamab-cxix), which was approved by the US Food

and Drug Administration for the treatment of relapsed/refractory diffuse large B-cell lymphoma (DLBCL) in August. (Also see "*Morphosys/Incyte's Monjuvi Wins Early US FDA Approval In Second-Line DLBCL*" - Scrip, 4 Aug, 2020.) The company has developed drugs that have been launched through partners, like *Johnson & Johnson*'s Tremfya, but Monjuvi is the first drug MorphoSys has launched, and it recruited a partner – *Incyte Corporation* – to co-commercialize.

"We were hit by the COVID pandemic in the middle of our launch preparations," chief commercial officer Roland Wandeler said. "I was impressed with how the team came together to rethink the way that we can engage physicians, to rethink the way that we can reach out digitally and to rethink the ways that we can combine personal interactions with the new virtual reality that we have in the pandemic."

The partners were able to hold 120 peer-to-peer education events in the area of hematology in the first three months of the US, he said, and had 6,200 interactions with health care professionals both virtually and in person.

Wandeler expects the future of drug commercialization will combine the new elements that have emerged from the pandemic and worked well with the in-person methods that worked well before. "I think it is that combination – getting that part right will allow us to be that much more effective," he said.

The new commercial model will be different than it was before the pandemic, IQVIA's Rickwood agreed. "What the new model is exactly going to be is still being worked through," she said.

As doctors have gotten used to remote engagement, it is likely here to stay. "For doctors, they appreciate the convenience that remote engagement or on demand engagement can give them," she said. And, she pointed out that the pandemic only accelerated a change that was already under way. "We should also not discount the generational change that was happening anyway," she added.

[Editor's note: This story is part of a series that will run in Scrip looking at how the pandemic impacted commercial activities. Stay tuned for additional articles on how companies adapted their promotional practices due to the pandemic.]