White Paper

Overcoming Pharma's Launch Performance Problem

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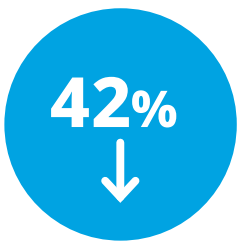
Introduction

The prescription medicine market recovered from the wild swings of the early pandemic with renewed volume growth, driven by generics. COVID-19 vaccines and treatments have created a substantial market — IQVIA estimates that the cumulative value of COVID-19 vaccines could be between $185 and 295bn to 2026.[1] However, value growth from recent non COVID-19 innovative launches is in trouble — from 2020 onwards, new innovative launches have, with certain exceptions, under-performed pre-pandemic benchmarks of launch sales performance in the countries that matter for global success: the US, EU4+UK, Japan, and China, accounting for more than 90% of the cumulative first five-year sales of the typical New Active Substance (NAS) launch.

This paper explores pharma's launch performance problem and the challenges of the new launch environment. Immediate environmental impact such as lockdowns have resolved, but patient backlogs, changes in healthcare professional (HCP) engagement and budget constraint will impact for years. For launch success in this environment, companies must have a clear understanding of these evolving dynamics and act early to adapt their launch plans to evolving patient, physician, and payor needs.

We assess which launch types are most resilient in the new environment, and how companies can successfully navigate the post-pandemic launch environment where existing challenges are compounded by reduced patient opportunity, physician engagement and market access.

Average sales for post-pandemic launches at month six are down by 19% on pre-pandemic benchmarks.



The most recent quarter's worth of launches for which we have six months of sales show continued underperformance: 42% below the pre-pandemic benchmark at month six.

Diagnosing the performance problem

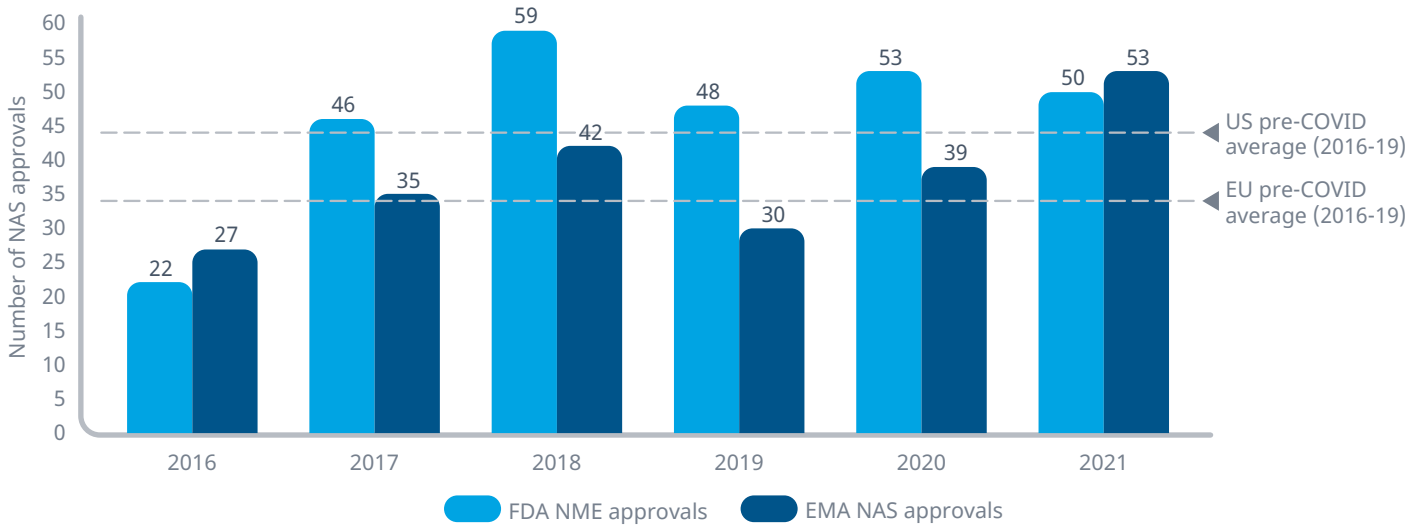
PRE-LAUNCH PROCESSES CONTINUE TO FUNCTION

The first step to commercial launch is regulatory approval, and for most of our key launch countries, a positive health technology/market access assessment to secure reimbursement and achieve favourable market share. We assessed the resilience of these key processes first.

1. **Regulatory bodies adapted well**
   New active substance approvals by both the FDA[2] and the EMA[3] were historically high in both 2020 and 2021 (Figure 1). Regulatory bodies were able to continue approving non-COVID-19 medicines on top of meeting additional demand to assess COVID-19 vaccines and treatments.

In 2021, innovative medicines were approved, launched and granted market access at rates above or closely similar to pre-pandemic benchmarks.

Figure 1:New active substance approvals by the FDA and EMA

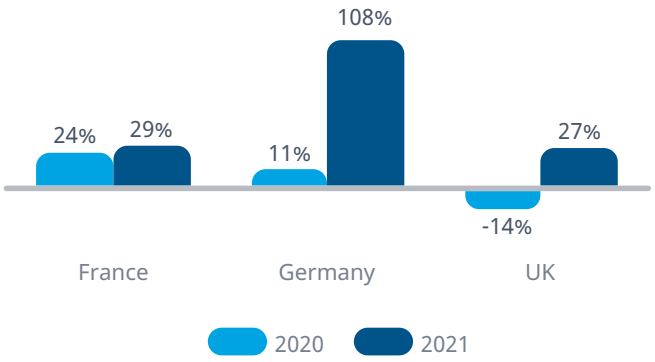


Source: EMEA Thought Leadership Secondary Research; FDA (Novel Drug Approvals for 2021 | FDA); EMA (https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines/medicine-evaluation-figures).
Notes: Pre-COVID average is the average number of approvals 2016-2019.

2. 2021 was a productive year for HTA bodies

To gain a favourable level of market access in Europe's Health Technology Assessment (HTA) driven-markets, companies must first seek an opinion from the country's HTA body. At the height of the pandemic (March-September 2020), HTA decision making slowed down in the UK and France (although not in Germany, where productivity remained high).[4] This disruption was short-lived- full year data for 2021 shows that the HTA bodies in France (HAS), Germany (G-BA) and the UK (NICE) had a strong year for decisions. In all three markets, the number of original and extension of indication product appraisals published in 2021 was above historic rates (Figure 2) and the largest it has ever been in all three countries.

Figure 2: Change in number of HTA decisions* published relative to pre-COVID baselines, %

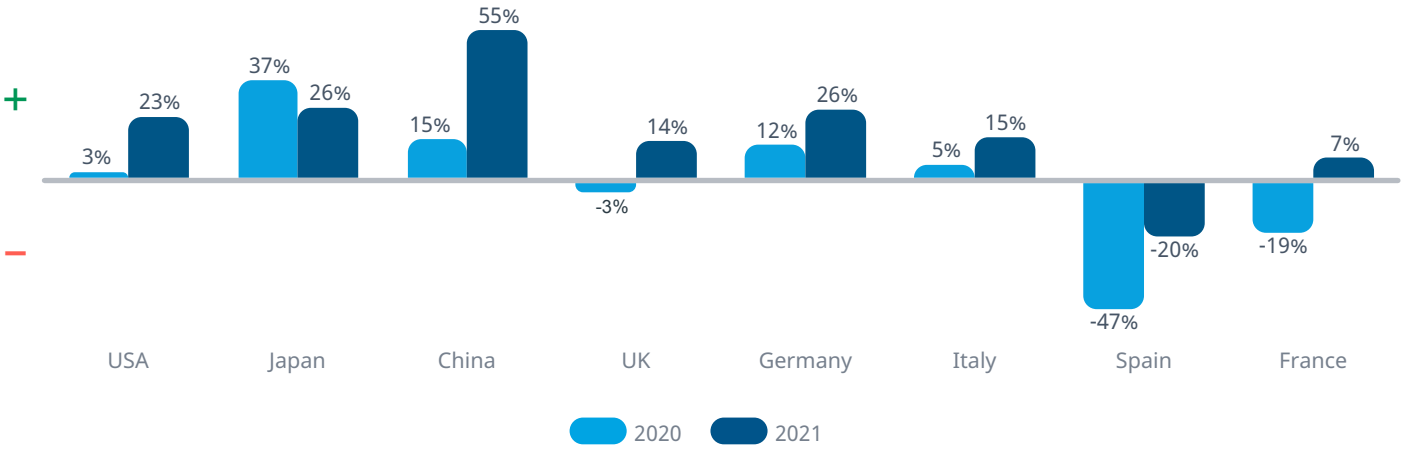


Source: IQVIA HTA Accelerator accessed July 2022.
Notes: *Original and extension of indication decisions published by NICE (UK), G-BA (Germany) or HAS (France). Pre-COVID baselines are the average number of decisions published 2016-2019.

3. Companies continue to launch

Companies could have chosen to delay launching New Active Substances in the early stages of the pandemic, but they did not — in fact, innovative medicines entered commercial channels, as measured by IQVIA at rates above or closely similar to pre-pandemic benchmarks, with only three substantial exceptions — France, in 2020, when New Active Substance entries were 19% below the 2016-2019 average, and Spain in both 2020 (47% below) and 2021 (20% below). The low number of launches in Spain was due to a combination of factors, such as the implementation of a new evaluation method creating delays at the health technology assessment level, misalignment between pharma and payers over prices, and company decision to launch later in Spain, rather than being a direct effect of the pandemic.

Figure 3: Change in the number of NAS launches in 2020 and 2021 relative to pre-COVID baselines, %



Source: MIDAS monthly Dec 2021, Secondary research.
Notes: The pre-COVID baseline is the average number of NAS launches between 2016-2019, except in China where it is the average number of NAS launches for 2017-2019. NAS launch defined as first appearance of sales of the molecule in a country.

PHARMA'S POST-PANDEMIC LAUNCH PERFORMANCE PROBLEM

Launches happened — but were they fulfilling their commercial potential? On average, across the eight countries that provide over 90% of the first five years' commercial potential for launch medicines, the answer is no.

Post-pandemic underperformance is substantial

Figure 4 shows month on month average sales across the US, China, top five Europe, and Japan for all New Active Substances, divided into time cohorts. Across the post-pandemic launches, the average sales at month six remain down by 19% on the pre-pandemic benchmark. Of course, determining absolute levels of launch value loss in the post-pandemic era is confounded by multiple variables but a simple calculation based on averages estimates that the post-pandemic launches could have collectively lost $440 million in first six-month sales compared to if they had been launched pre-pandemic.

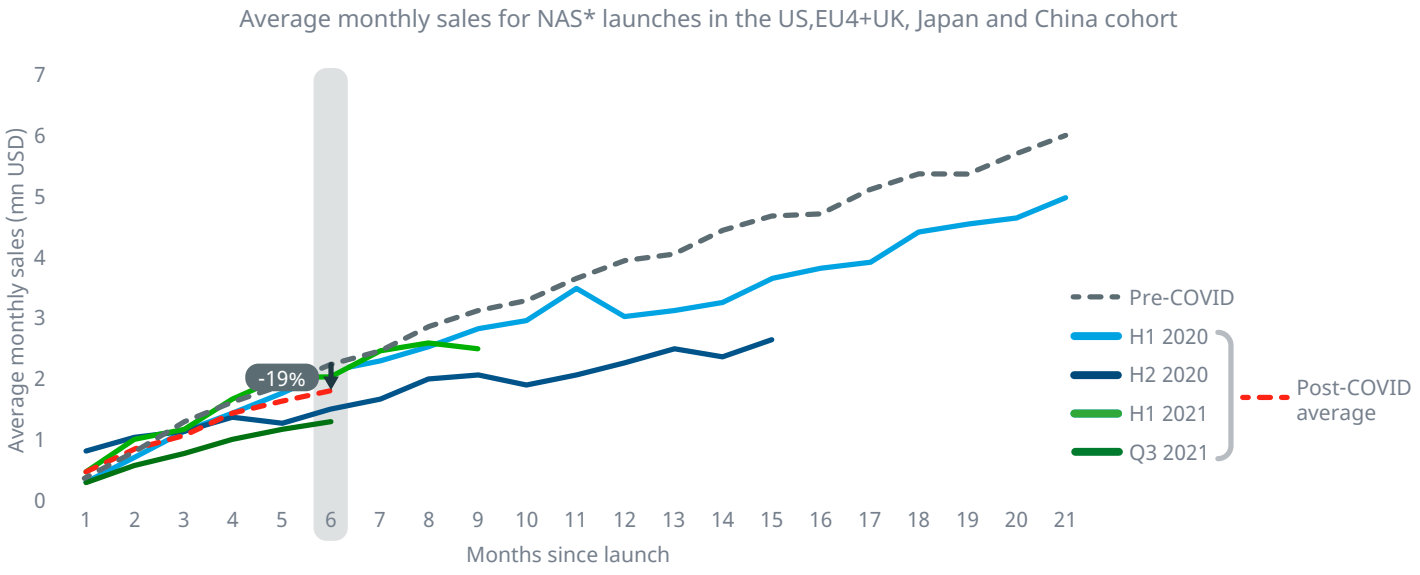
Post-pandemic underperformance endures

Breaking down the post-pandemic launches into time cohorts shows that on average, launches of both halves of 2020 underperformed. The average for the first half of 2021 did seem to revive pre-pandemic levels in the first six months, but that was heavily influenced by the outstanding performance of one launch: Wegovy, an obesity treatment, in the US. The most recent quarter's worth of launches for which we have six months of sales show significant underperformance: 42% below the pre-pandemic benchmark. Furthermore, the 2020 post-pandemic launches, for which we now have up to 21 months of sales, show continued average underperformance.

Post-pandemic underperformance impacts all countries but differs by product type

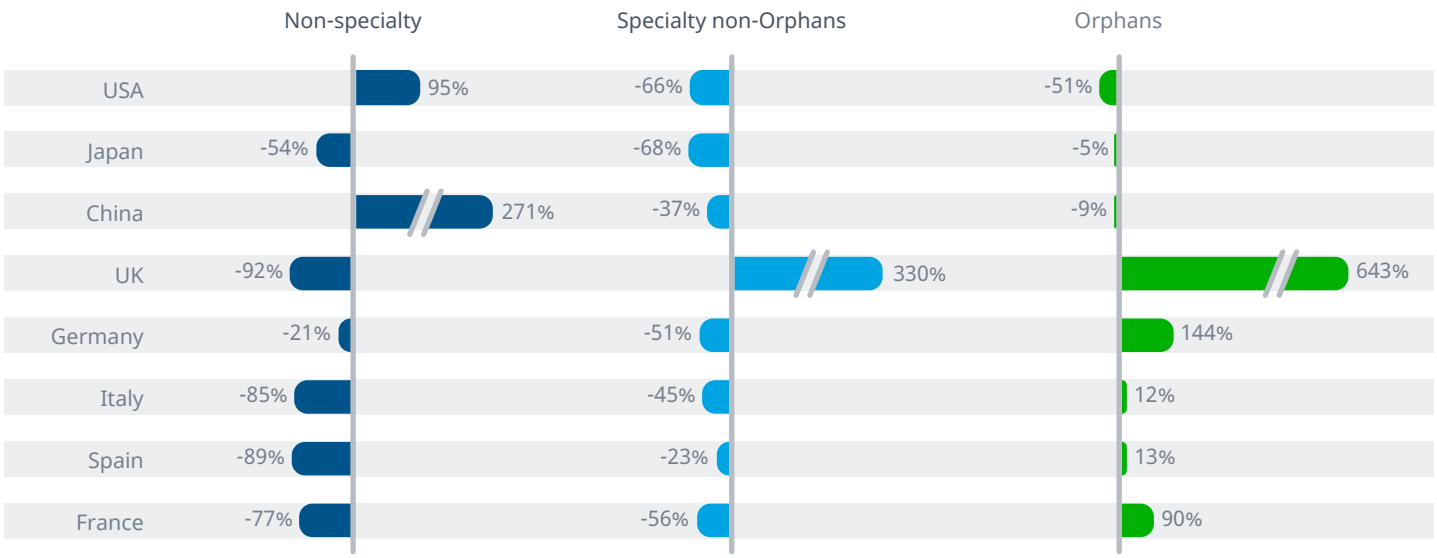
Country-level analysis found that the pandemic performance impact varies by launch type (Figure 5). For non-specialty medicines, underperformance is evident across all countries, except a few outstanding launches in the US (Wegovy, Ubrelvy, Nurtec) and

Figure 4: Performance of innovative launches pre-COVID versus post-COVID



Source: IQVIA EMEA Thought Leadership, IQVIA MIDAS March 2021.
Notes: Rx only; USD in CER; *Includes NAS launches only, except for Wegovy which is included even though semaglutide is not NAS because it is a major US launch in a new therapy area; Pre-pandemic launches: Mar-15 to Sep-19; Excludes Hep C products and COVID-19 Vaccines and Treatments; The pandemic-impacted cohorts have smaller sample sizes than the pre-pandemic cohorts (N numbers: Pre-COVID = 1017, H1 2020 = 131; H2 2020= 109; H1 2021 = 140, Q3 2021 = 71). Note that averages can be heavily influenced by a small number of launches.

Figure 5: Average first 6-months sales for post-pandemic NAS launches versus pre-pandemic benchmarks* by country and product type



Source: IQVIA EMEA Thought Leadership; IQVIA MIDAS March 2021; Rx-only.
Notes: Includes NAS launches only; Excludes COVID-19 Vaccines and Treatments and Hep C; Pre-pandemic launches: Mar-15 to Sep-19; *Pre-COVID-19 benchmarks are the average six months sales of pre-pandemic launches (Mar-15 to Sep-19) in a product category (specialty or primary care) in a country. For the full benchmark methodology refer to the appendix. Note that averages can be heavily influenced by a small number of launches.

China (Ozempic). Non-orphan specialty launches also show average underperformance across countries since the pandemic, except for the UK. The outperformance of the UK was driven by a few outstanding launches (discussed in Chapter 3) and a low pre-COVID-19 benchmark of uptake in the first six months (the lowest of any of the European countries). Orphan launches prove most resilient in the post-pandemic launch environment, due to a combination of factors such as high levels of unmet need in small and well-defined patient populations, and two standout post-pandemic European launches (Zolgensma and Trikafta).

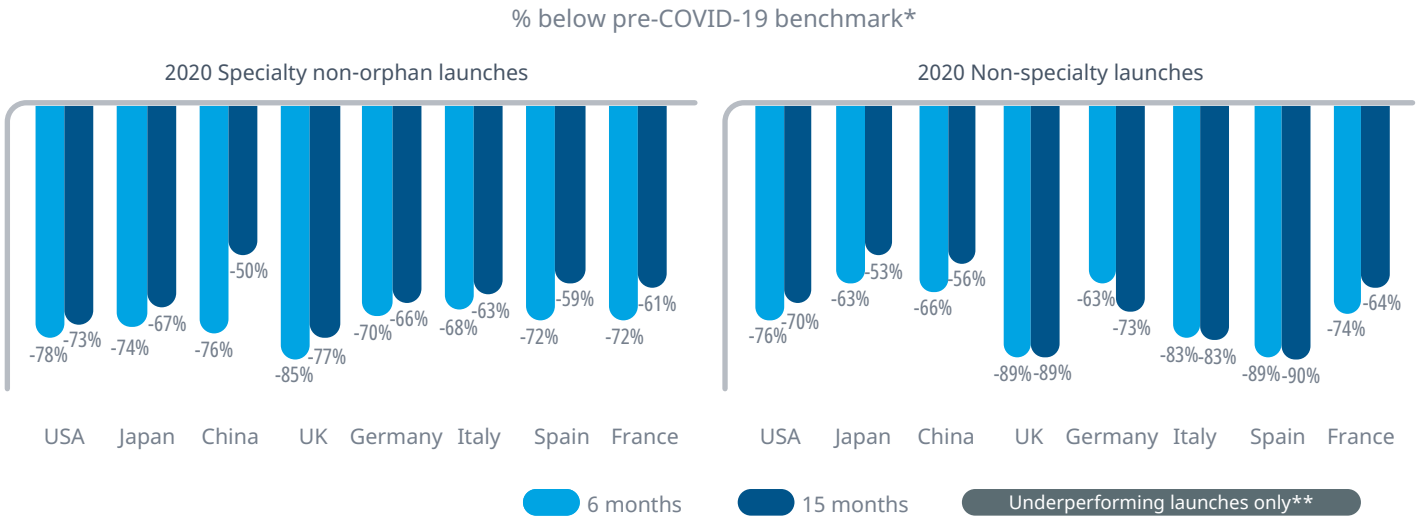
Post-pandemic underperformance could be difficult to change

Since the first Launch Excellence white paper IQVIA published in 2007, we have repeatedly found that fewer than one in five launches where the early trajectory is weak are able to improve 24 (or 18) months on. This six-month window has stood the test of time, proving to endure through launch type, and launch environment evolution. Never has the environment changed so much, so quickly as in the pandemic, and we do not yet have enough data for the definitive answer, but if the six-month window continues to hold true post-COVID-19, the chances of these launches recovering are low.

Underperforming 2020 launches have not recovered from a slow start

On average, the underperforming non-specialty and specialty non-orphan launches of 2020 show modest improvement in many countries fifteen months later (Figure 6), but no rebound. Although we do not yet have a sufficient sample of post-pandemic launches with 18 months of sales to repeat the six-month window analysis, this is early evidence this window still applies. Recovery may be possible if the bulk of the COVID-19 backlog of patients still needs to be addressed, which we explore in Chapter 2.

Figure 6: Average cumulative sales for underperforming 2020 launches at 6-months and 15-months vs. pre-COVID benchmark, by product type



Source: IQVIA EMEA Thought Leadership, IQVIA MIDAS March 2021.
Notes: Rx only, NAS launches only; Excludes Hep C products and COVID-19 Vaccines and Treatments; *Pre-COVID-19 benchmarks are the average six months or fifteen months sales of pre-pandemic launches (Mar-15 to Sep-19) in a product category (specialty or primary care) in a country; **Underperforming launches are launches that performed below benchmark at 6-months. For the full benchmark methodology refer to the appendix.

Challenges of the post-pandemic environment

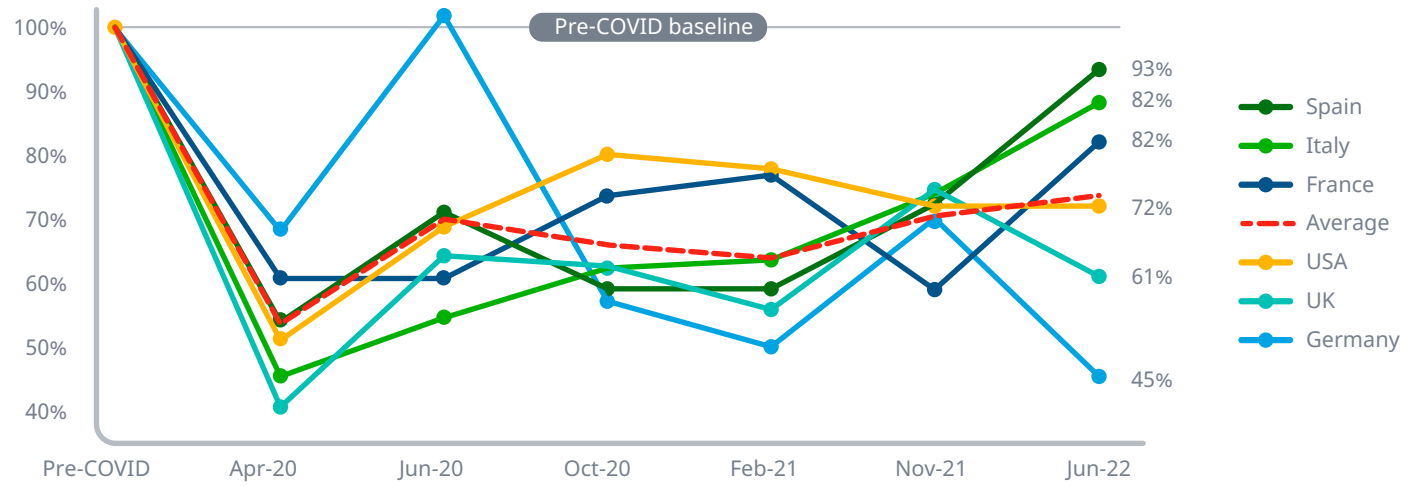
We see this pattern because of a perfect storm of pandemic initiated factors, which combined (and continue to combine) to create an environment that hurts the sales performance of launches more than inline medicines. To launch successfully, companies must have a clear understanding of these evolving dynamics and act early to adapt their launch plans.

1. THE PATIENT JOURNEY HAS PERMANENTLY CHANGED

Patient opportunity reduces as journey to diagnosis and treatment becomes lengthier, leakier, and more complex

Treatment and diagnosis backlogs still linger and in some disease areas some sufferers may never be diagnosed and treated. The therapy area with the most innovative launches, Oncology, sees significant treatment backlogs across markets, due to delays and cancellations in screening, diagnoses, treatment, and surgeries, resulting in long waits and anxiety for patients. IQVIA models based on US claims data estimates that over 30 million screenings for four common tumour types (colorectal, lung, breast and cervical) were disrupted, risking delayed or missed diagnoses for over 58,000 US patients.[5] IQVIA primary research shows two years into the pandemic the number of cancer patients seen by oncology specialists improves but has yet to return to pre-COVID-19 levels in any of the top 5 European markets or the US (Figure 7).[6] NHS England reported that in April 2022, the number of patients receiving their first cancer treatment was still 8% below April 2019 levels.[7] These delays can mean patients present for treatment at later, less curable stages. In the UK, record numbers of patients are now coming forward with symptoms, waiting times are longer than ever and backlogs are the highest they have ever been.[7]

Figure 7: Oncology percentage caseload versus pre-pandemic



Source: IQVIA Primary Market Research Impact of COVID-19 on the Treatment of Cancer Wave 6, June 2022: Q1: After the COVID-19 outbreak, are you seeing fewer hematology/oncology patients per week?

Patients that are already diagnosed can also not receive the benefit of a new launch. Reduced face-to-face visits means that opportunities for HCP visits to evaluate treatment progress reduce, meaning some patients receive treatments that may no longer be suitable. Since these patients are already in the system, they are at the biggest risk of being forgotten, particularly given the backlogs of patients with no diagnosis at all.

HCPs remain reluctant to prescribe new launches remotely

The initial lockdowns prevented many patients from seeing doctors face to face. Telemedicine and other remote care rose dramatically in many countries, providing a route to managing ongoing care for many patients. Telemedicine fell back from initial lockdown highs, but IQVIA primary research found that 80% of HCPs in Europe and the US have permanently shifted to more frequent remote patient management (in Italy and the UK it is more than 90%), and around half are using virtual tools for patient monitoring.[8] The issue for innovative launches is that most doctors polled by IQVIA consistently state that whilst they are happy to manage many aspects of patient care remotely, they want to see the patient face to face when prescribing a newly launched medicine.

More conservative prescribers stick to what they know

In an environment where prescribers are reluctant to prescribe new medicines remotely, launches representing an incremental improvement for a condition with existing treatments are more challenged than launches for high unmet need conditions (and indeed, we saw that on average orphan medicines are the most resilient group in the pandemic). Similarly, this reluctance means that new patients (that are not yet being treated at all) are more likely to be prescribed new medicines than patients that are already being treated. In the overall US market, new therapy starts recovered from the 2020 dip, surpassing historical levels in 2021. However, switch patients remain almost 8% lower than historic benchmarks.[9] Whilst the US has begun to address backlogs in diagnoses, overall, physicians remain more reluctant to switch stable patients than before COVID-19 (at an aggregate level). In an uncertain environment with fewer face-to-face visits, prescribers are, where possible, more conservative.

2. QUANTITY AND QUALITY OF PHARMA'S HCP INTERACTION HAS PERMANENTLY CHANGED

Pharma still has less HCP interactive time in all markets except the US

Launching medicines requires interaction with doctors to raise awareness, answer questions and build knowledge. Crucially, the total amount of interactive promotional time, remote and face to face, that pharma has with doctors has not yet recovered to pre-pandemic levels in Europe, Japan, or China (Figure 8). This impacts launches most.

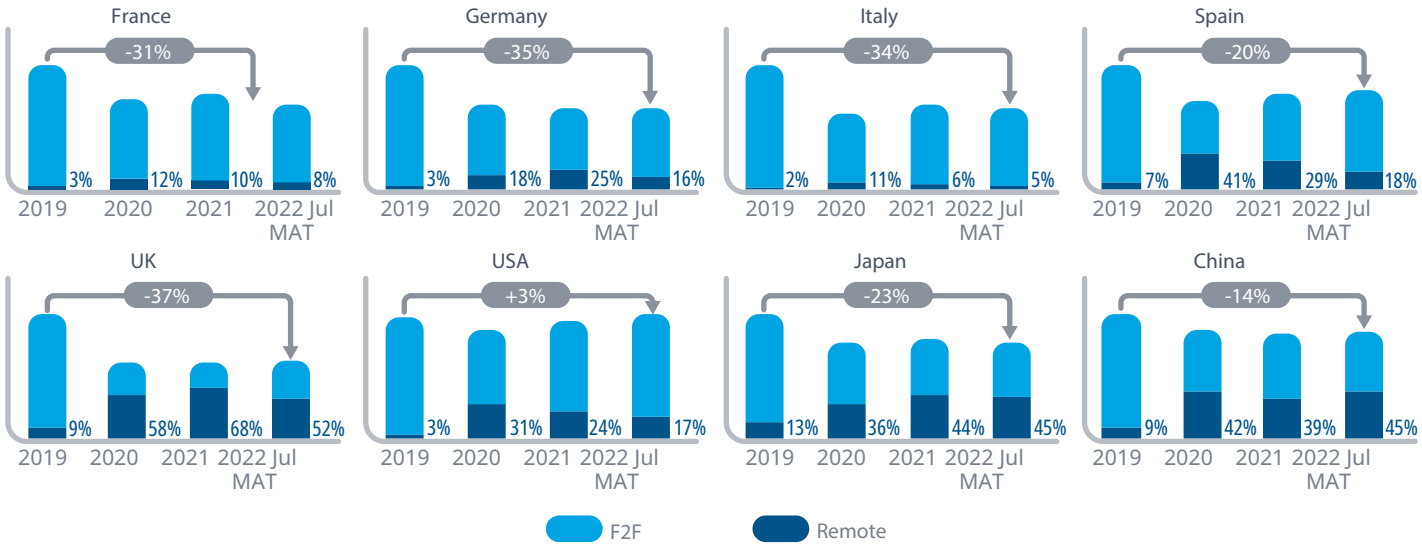
Traditional channels alone do not suffice

Face-to-face engagement between pharmaceutical reps and doctors has always been extremely important to launch, historically considered essential for driving launch uptake. Promotional channel mix tilted dramatically to remote/digital during 2020 and has remained permanently more hybrid. IQVIA analysis shows that a higher proportion of one-to-one interactive engagements are digital for launches compared to all products across EU4, UK and the US. We hypothesize that pharma companies with limited opportunity to reach HCPs face-to-face are out of necessity broadening channels of engagement.

Companies had to reach beyond traditional channels to reach some HCPs anyway, and IQVIA's primary research finds a significant share of HCPs indicated that virtual interactions would be largely sufficient in the future.[10] While many HCPs still value face-to-face interactions highly, pharma must invest in digital capabilities to supplement (but not replace) face-to-face interactions if they want to reach this segment of the HCP population. In an environment where companies are less able to access HCPs, the best channel may be the one that enables the interaction. This means that pharma companies must build capabilities and infrastructure to interact with HCPs across all available channels.

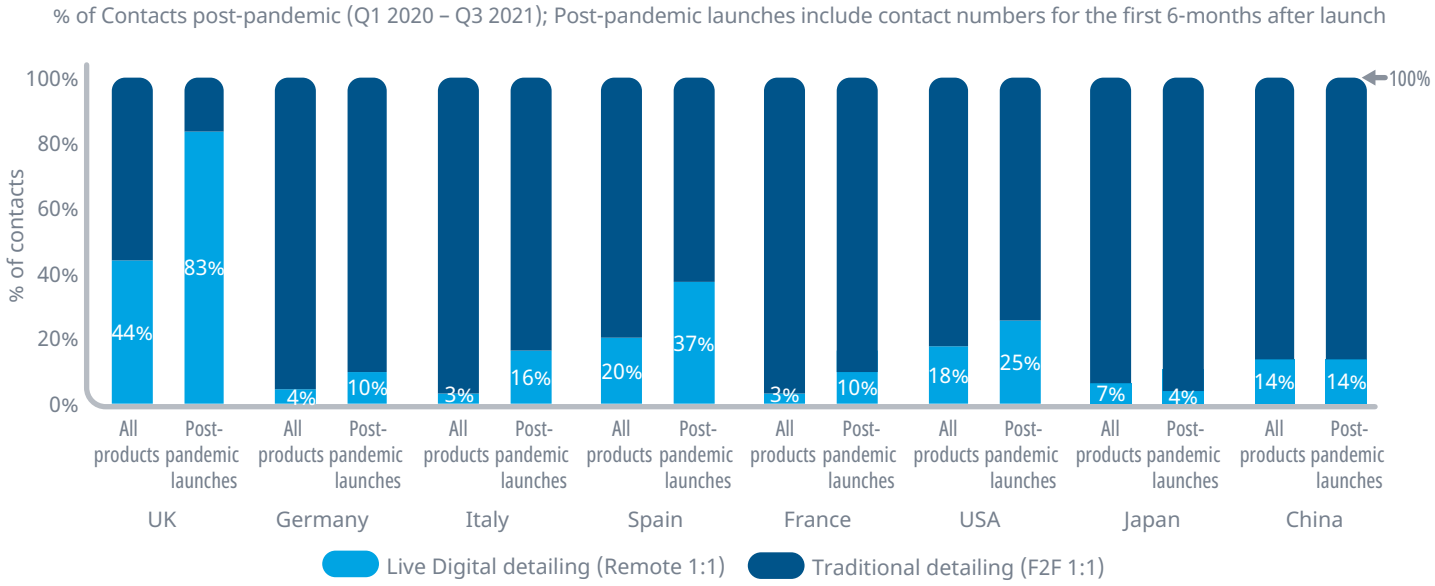
IQVIA's previous research has shown that for pre-pandemic launches (2014–2018), the more commercially successful launches for both specialty and primary care products were also the more digital launches in the lead seven markets (US, EU4, UK, Japan), making the

Figure 8: Share of F2F and remote HCP interaction in promotional volume (contact numbers)



Source: IQVIA ChannelDynamics, July 2022.
Notes: F2F includes F2F detailing and F2F meetings, Remote includes phone detailing, e-detailing (live), e-meetings (live).

Figure 9: Post-pandemic digital versus traditional share of 1:1 product details for all products versus NAS launches by country



Source: IQVIA EMEA Thought leadership, Channel Dynamics.
Notes: Post-pandemic launches are NAS launches in a country from Q1 2020-Q3 2021. Volume in terms of contact numbers; Digital – detailing (remote with rep), Traditional – detailing (face to face).

case for digital investment even before the pandemic. Although we do not yet have enough data to determine 'excellent' post-pandemic launches (according to our historical excellence criteria which evaluated launches at 18 months-2 years in each country market), hybrid engagement, including digital, is integral to post-pandemic launch success. The optimal engagement strategy should draw on a mixture of digital and traditional methods to disseminate high-quality evidence.

3. WIDER ECONOMIC CHALLENGE WILL AFFECT BUDGETS FOR INNOVATIVE MEDICINES

New policies contain costs in the largest prescription markets

The US, Japan, and Germany (three of the largest four prescription medicine markets) are already heading to increase cost-containment measures. In the **US**, drug pricing reforms appear more likely than at any time in recent years under the Inflation Reduction Act. This bill could allow the Federal Government to negotiate the price of a limited number of high-cost Medicare drugs and proposes that manufacturers pay Medicare rebates on price increases above inflation. New products are unlikely to be target medicines in their launch period, but longer term impacts on the types of launch entering the US market (and likely, the world market) are possible.

In **Germany**, a cost-containment package (the Statutory Health Insurance Finance Stabilisation Bill) is expected to be implemented, estimated to cost pharma four billion euros.[11] Finally, in **Japan**, additional "off-year" price cuts were implemented in 2021 (beyond the usual biennial price revisions) and will likely occur again in 2023.[12] There is still uncertainty around all the proposed policies, but each could impact the attractiveness of these launch markets.

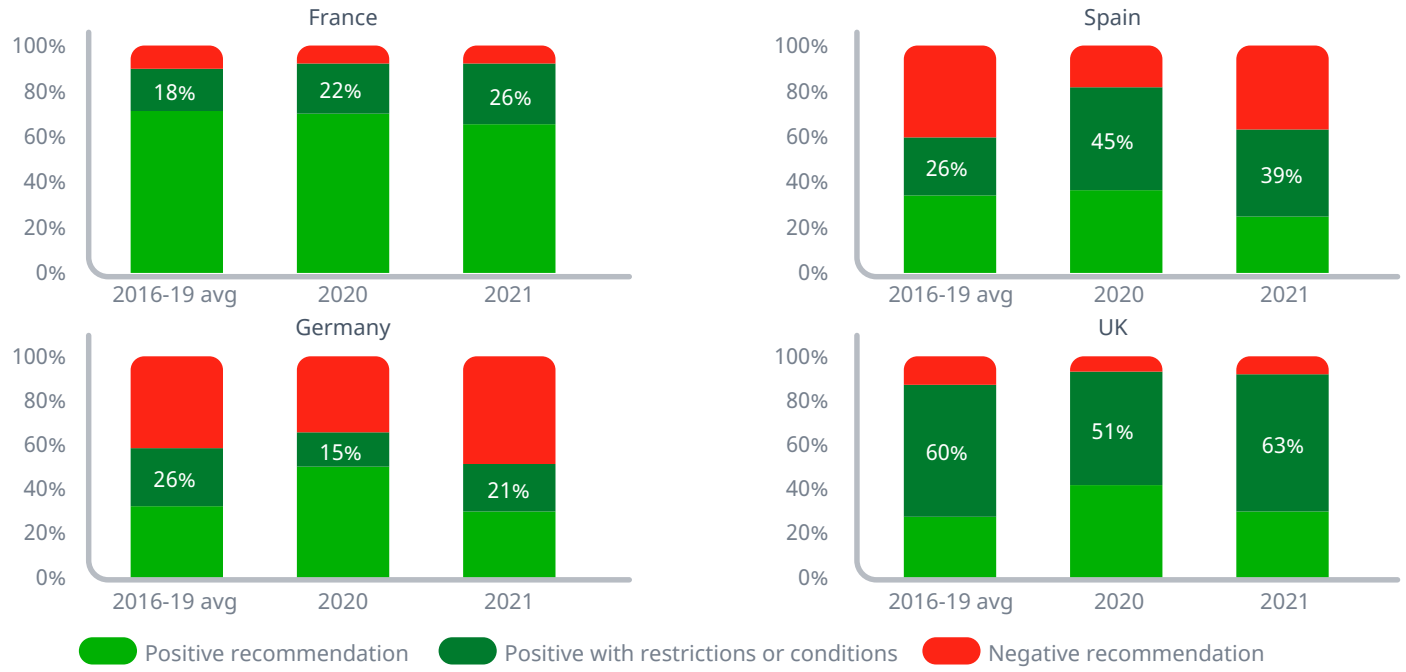
The importance of China as a launch market will continue to rise (Figure 1 shows that China had the highest growth in the number of innovative launches in 2021 versus pre-pandemic), although profitability continues to be a challenge as securing inclusion on the National Reimbursement Drug List typically requires heavy discounts.

Market access and funding becomes more challenging

In European markets there are growing numbers of conditions or restrictions alongside a reimbursement decision, limiting patient opportunity more. IQVIA's HTA Accelerator dashboard shows that the proportion of recommendation decisions (original and extension of indication) published that were positive with restrictions or conditions by health technology assessment bodies has been increasing since 2018 across 16 European countries (from 27% in 2018 to 37% in 2021). In France and Spain the proportion of decisions that were positive with restrictions reached the highest recorded levels in 2021 and 2020 respectively (Figure 10). We do not see a historically higher proportion of restricted recommendations in Germany (G-BA) or the UK (NICE) in the post-COVID-19 years, however the UK has used restrictions and conditions for years on as many as 65% of decisions. In Germany, reforms under the statutory health insurance (SHI) savings bill will harden the market access environment, particularly for orphan drugs which will increasingly require full HTA assessment once they surpass 20 million euros in yearly sales, rather than the current 50 million euros.[11]

The types of conditions or restrictions that are recommended by HTA bodies varies significantly by country, for example in France medicines are most often recommended for subgroups of the approved indications, whereas the UK uses many different types of conditions including subgroups, patient characteristics, line of treatment and failure of specific treatments. This growing likelihood of a gap between the approved label population and what healthcare systems are willing to fund either permanently limits potential or extends launch, as companies work to demonstrate the value required for full market access. The trend was not originated in the pandemic, but is undoubtedly reinforced and extended by it, and by the current economic crisis.

Figure 10: Proportion of national HTA decisions* that are positive with restrictions or conditions



Source: IQVIA HTA Accelerator accessed July 2022.
Notes: *Original and extension of indication decisions published by national HTA bodies NICE (UK), G-BA (Germany), HAS (France), AEMPS (Spain).

Achieving post-pandemic launch excellence

COMMON CHARACTERISTICS OF RESILIENT LAUNCHES

Products that reduce healthcare burden have a new advantage

Whilst backlogged health systems are a challenge for most launches, products with certain characteristics benefit. Medicines that can be self-administered, keep patients out of hospitals or save HCP time can help to address backlogs, and improve care. In the UK, guidance was introduced for oral and subcutaneous medicines in the pandemic (e.g. NICE Guidance 161[13] for cancer patients) that recommends, where possible, use of these routes of administration above IV treatments. IQVIA's primary research found that 77% of surveyed oncology specialists in the UK reported a change of treatment protocol to substitute oral oncologics, wherever possible (much higher than in other surveyed countries which ranged from 25% in Germany to 49% in Spain).

Launches that reduce the healthcare burden and have outperformed include:

- Roche's new combination subcutaneous breast cancer treatment, **Phesgo**, which reduces administration time from 2.5 hours to five minutes, and oral cancer agents such as **Calquence**. Both outperformed in the UK and Germany. A deal with NHS England as part of a government strategy to fund COVID-friendly drugs meant Phesgo had very strong and rapid uptake in the UK.[14]
- **Darzalex faspro**, the subcutaneous version of IV Darzalex is excluded from our analyses as it is non-NAS, however since launching post-pandemic it has had a very strong uptake. According to IQVIA MIDAS data, 83% of US sales and 91% of Japanese sales are now from the subcutaneous forms as of June 2022.
- **Reblozyl** in Germany, which significantly decreases blood transfusions[15] (indicated for the treatment of transfusion-dependent anaemia associated with beta thalassaemia).
- **Ultomiris** in the UK, which reduces the need for blood transfusions versus existing treatment (Soliris), as well as offering less frequent IV administration (every 8 weeks versus every other week with Soliris).[16]

Improving convenience has always been a differentiator for new medicines, but it has historically focused on convenience for the patient, rather than convenience for healthcare systems. Many companies are now already developing subcutaneous formulations for recent post-pandemic launches (for example, Horizon's Tepezza for thyroid eye disease and GSK's Cabenuva for HIV).[17]

Resilient launches have a strong patient pipeline and strong clinical story

Orphan medicines and other specialty non-orphan launches in cancer and HIV have been among the most consistently resilient, across countries, over the course of the pandemic. These launches all address high unmet need in small, well defined, and, crucially, mostly pre-identified patient populations. Therefore, the challenge of patient journeys disrupted or abandoned by the pandemic impacted less. Healthcare systems also remained highly motivated to fund and deliver these launches, and patients are highly motivated to seek treatment. Launches resilient at six months for these reasons include many orphan medicines, for example **Tepezza** (thyroid eye disease), **Trikafta** (for cystic fibrosis), **Rezurock** (for transplant patients), as well as non-orphan launches in HIV and oncology such as **Dovato** (HIV), **Polivy** (DLBCL) and **Lumakras** (the first and only targeted treatment for KRAS G12C-mutated NSCLS).

Consumer-driven launches outperform in the US

Outperforming launches in the US are often consumer-driven products. The two oral migraine treatments, **Nurtec** and **Ubrelvy** (2020 launches) and **Wegovy** (2021 obesity treatment) are outstanding pandemic launches, enabled by specific environmental factors: direct-to-consumer advertising (prohibited in Europe),

the obesity epidemic in the US and voucher schemes which ensure patient affordability (but at the expense of launch profitability). **Nurtec** and **Ubrelvy** did strongly during the first lockdowns by meeting patient awareness and demand with a fully remote patient journey, from consultations with physicians through to prescription and medication delivery. The pandemic also accelerated the rise of online prescribing platforms in the US, which allow a completely virtual patient journey from consultation to prescription and insurance authorisation and prescription fill and delivery. These platforms are often not for launch products, but some, such as the contraceptive gel **Phexxi**, approved 2020 in the US, have made them a part of their launch campaign.

WHAT MUST COMPANIES DO TO ACHIEVE POST-PANDEMIC LAUNCH EXCELLENCE?

1. **Understand the patient journey and identify strategies to strengthen the path to diagnosis and treatment**

Pharma companies preparing launches must build early, detailed insight into how patient journeys have changed post-pandemic, identifying and addressing barriers to diagnosis and treatment. The more complex the patient journey, as is often the case for rare disease and highly specialist treatments, the more opportunity for disruption.

Widening the top of the funnel

Strengthening patient journeys starts at the "top of the funnel", motivating HCPs to identify patients and patients to seek care, for example with awareness campaigns (for common conditions), direct to consumer advertising (US), and improving patient support programmes. Screening programs are a powerful way to build a patient pipeline for some diseases and have likely been critical to the success of two outperforming products for spinal muscular atrophy (SMA): **Zolgensma** (a gene therapy) and **Evrysdi** (an oral agent). Since treatments for SMA became available, screening programs are now approved in six European countries (including Germany), with ongoing pilots in many other European countries including the UK, Spain and Italy.[18] The European Alliance for Newborn Screening in SMA (supported by Novartis and Roche) is advocating for all European countries to include a test for SMA for all newborn children by 2025.

HCP awareness of a condition and launch is also critical. Horizon's **Tepezza** performed exceptionally well in the first six months in the US, driven by fast adoption amongst ocular specialists familiar with the disease and highly motivated to treat their patients. Additionally, TV adverts drove viewers directly to Tepezza websites, where patients could use Horizon's physician finder to find a local doctor to treat their condition (the website even uses a special font designed for people with poor vision and a feature to read the page aloud).[19] Since Tepezza was re-launched after a temporary supply issue, sales have been slower, reflecting a tougher challenge to capture patients with a more complex journey that is referred for treatment through ophthalmologists and endocrinologists.

Medical Affairs, long a support function, was already becoming a strategic one with the rise of specialty launches. Medical Affairs becomes even more vital when changes in patient journeys must be understood and HCP awareness raised.

Supporting healthcare delivery

Launching companies also need to help health systems identify patients stuck on inadequate treatment by supporting nurses and HCPs, leveraging digital/remote monitoring devices, smart tech and wearables. Limited health system capacity exacerbated by the pandemic is a significant challenge to accessing these patients treated but not optimally treated. The switch market is a challenge to access.

Companies are devising new strategies such as partnerships with homecare providers and specialty pharmacies for medicine delivery outside of hospital. Horizon's CEO said that the decision to find alternative sites of care outside of the hospital for **Tepezza**

administration (injectable treatment for thyroid eye disease) was fundamental to the product's initial US success during the pandemic.[20] GSK is currently making this pivot with **Cabenuva** (injectable HIV treatment) in the US. Despite strong demand for **Cabenuva**, a lack of capacity in the physician's office (a lack of nurses and capacity to manage the reimbursement process) has been a barrier to uptake. GSK is working to support workflows and expand the injection to alternative sites of care.[21] The capacity challenge will grow as there will likely be an increasing demand for healthcare and a decreasing number of healthcare workers — according to an Elsevier survey, 74% of clinicians predict a shortage of nurses and 68% predict a shortage of doctors, as almost one third of respondents said they were planning to leave their role in the next few years.[22]

Understanding a launch's impact on stretched health systems

Conversely, pharma companies may need to be mindful that launches could cause additional burden to health systems and HCPs. Limited HCP time in the UK could be hindering the uptake of **Leqvio** (a first-in-class siRNA cholesterol-lowering medicine). Novartis' world-first population health agreement with NHS England targets treating 300 000 high-risk patients over three years with a substantial discount.[23] This population health management approach has the potential to be hugely beneficial to patients and health systems, and we expect to see health systems move towards preventative health care management more to achieve long-term benefits– however it requires extra work (identifying high-risk patients, buying stock, scheduling and injecting them, and rescheduling for every 6 months) at a time when health systems are in survival mode and GPs are at capacity. Novartis is responding with strong efforts to engage GPs (the company has recently launched a large-scale education campaign in the UK), which may positively impact the situation.

2. Optimising every engagement opportunity

Reduction and change in interactive HCP engagement is a major challenge for launch, as the amount of interactive engagement (virtual and face-to-face) remains below pre-pandemic levels across Europe, China and Japan, only recovering in the US. Pharma companies must seek every interactive opportunity they can get, and optimise on every interaction. To achieve launch success, companies must focus on:

- **Engagement via a range of channels:** Most HCPs have been exposed to a wider range of engagement channels because of the pandemic than ever before, and this continues to evolve. Companies must build the capacity and expertise for engagement via all channels, and then orchestrate across them for optimal impact.
- **Stream of relevant content:** Even prior to the pandemic, IQVIA showed that excellent launches are associated with a superior level of Real World Evidence publication productivity.[24] In an environment where interactive engagement opportunities are scarce, RWE is a powerful tool, providing a compelling reason to engage with HCPs and rebuild relationships weakened by the pandemic, as well as providing evidence based insight on the value and relevance of a launch.
- **Detailed customer focus:** Personalise content and messaging to individual HCP needs. IQVIA's 2022 Channel Preference research found a low alignment between a physician's preferred channel and the actual received channel. HCPs have different preferences on when, where and how they receive information, and a granular understanding of physician preferences will be key to both securing and optimising on engagements.

For more insight, IQVIA's recent white paper *Riding Out the Storm: The future of post-pandemic customer engagement*[i] described six enablers for future customer engagement models which will be at the heart of future successful launches.[25]

[i] IQVIA white paper: Riding Out the Storm: The future of post-pandemic customer engagement (https://www.iqvia.com/-/media/iqvia/pdfs/library/white-papers/riding-out-the-storm-the-future-of-post-pandemic-customer-engagement.pdf)

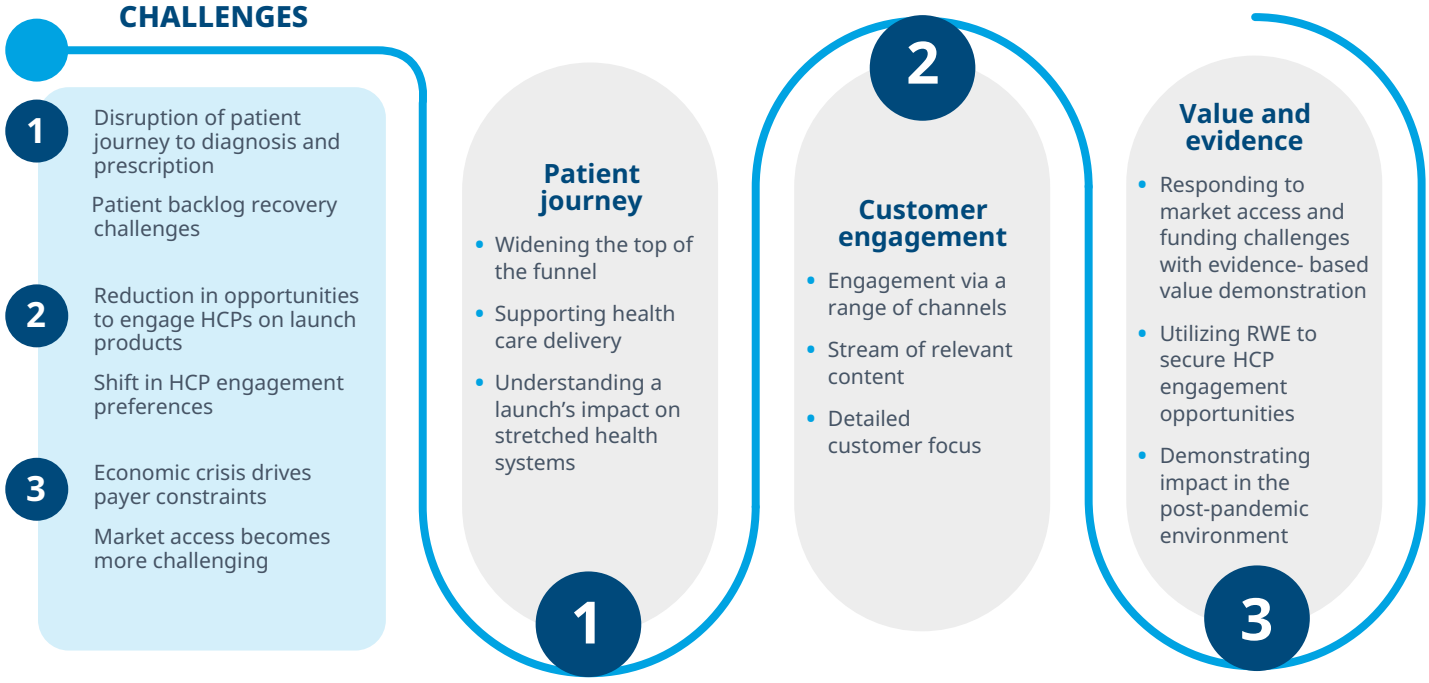
3. Pharma must build a strong integrated evidence strategy

A strong integrated evidence strategy will be even more important post-pandemic. As well as helping rebuild HCP interactive engagement opportunities, RWE is vital to address stricter market access and funding decisions. Medicines budgets for innovation will become more restrained, and the access evidence bar will continue to rise. With access often, as we have found, restricted to sub-populations for new launches, RWE should be used to identify the populations where the product is most effective and make the case for expanded access.

IQVIA analysis has shown that in rare diseases, submissions for approval that include RWE are approved faster by most approval pathways than those that don't.[26] However, importantly, payers are now starting to openly endorse use of RWE to supplement RCT data. The latest NICE Health Technology Evaluation Manual formalises the acceptability of RWE as a source of evidence[27], and there are now examples of outperforming launches where RWE was successfully used to support HTA submissions post-pandemic (for example, **Zolgensma** and **Evrysdi** in England and France). In Spain, patient registries are required for a growing number of expensive medicines, including post-pandemic launches **Yescarta** (outperformer) and **Polivy** (launched Q4 2021), and this trend will likely continue. This is supported by Valtermed, a data information system setup by the Spanish government, which enables payment-by-results agreements to pave the way for the reimbursement of expensive medicines. Germany has also mandated the collection of RWE for **Zolgensma**, and likely more post- pandemic launches (**Evrysdi** and **Tecartus**).

An August 2022 IQVIA survey of 911 specialists across the lead five European markets and the US showed 54% of respondents wanted more real-world research into differences in outcomes of remote treatment.[28] Beyond supporting market access and improving HCP interactivity, RWE will be a fundamental way for pharma companies to evidence improved patient outcomes in the post-pandemic care environment, such as quality of life improvements over standard of care, and the reduction of burden on health systems, both features of resilient post-pandemic launches.

Figure 11: The Three Pillars of Launch Excellence to achieve post-pandemic success



THE FORWARD VIEW

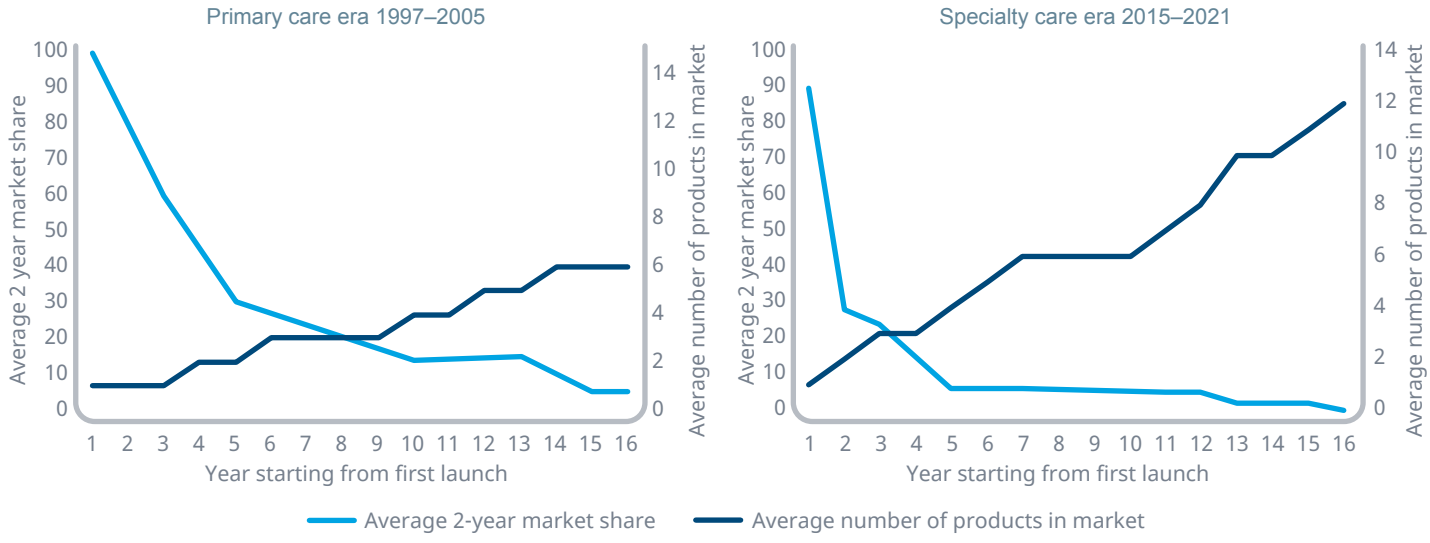
The pipeline of innovative launches remains strong — 290–315 innovative launches are expected to launch globally over the next five years to 2026 (averaging 54–63 per year, like the last 5 years).[1] Most will be specialty launches. Orphan medicines will continue to represent a high share of innovation, and oncology will continue to be the dominant therapy area, with 100 new oncology drugs expected to launch globally by 2026. Around 40% of the oncology pipeline is for rare cancers, including new generation therapeutics (cell, gene and RNA-based therapies, including CAR-T).[29] Advanced therapy medicinal products (ATMP) will become increasingly commercially important, as will digital therapeutics.

For these launches, many of the post-pandemic launch challenges are particularly relevant - backlogs are particularly significant in oncology, and the hardening market access and funding environment will be particularly difficult for expensive orphan and advanced therapies. Where highly novel treatments like ATMPs require re-engineering of healthcare delivery, this may be a particular challenge in the resource stressed healthcare environment.

FUTURE-PROOFING LAUNCH TO 2030

Even without pandemic challenges, the innovative launch environment is increasingly harsh. As the market switched from launches in primary care markets to those in specialty care, launches saw competition enter ever faster in key therapy areas and the market share achievement of follower launches at two years dwindled. Among the consistently most valuable therapy classes of 1997–2005 were Statins, Proton Pump inhibitors, SSRI antidepressants, Erythropoietins and Angiotensin II antagonists — mostly primary care. On average these therapy areas saw up to 6 new launches in 16 years and

Figure 12: Increasing competition is reducing Market Share 2 years post-launch



Source: IQVIA EMEA Thought Leadership analysis.
Notes: Therapy classes are the top therapy classes in each era, globally. Primary care era Therapy areas included: Statins: C10A1 PPI: A2B2SSRI antidepressants: N6A4 Erythropoietins B3C0 Angiotensin II antagonists C9C0. Specialty care era Therapy areas included: HER2 MAbs: L1G3 HIV Anti-virals: J5C9 Hepatitis C antivirals: J5D3 Interleukin inhibitors: L4C0PD-1/L1 MAbs: L1G5.

products up to the 5th to market could expect more than 10% share of the market at two years. By the specialty era, when the leading classes were HER2 MAbs, HIV Anti-virals, Hepatitis C antivirals, Interleukin inhibitors and PD-1/L1 MAbs, the average number of competitors at 16 years doubled to 12 and only the first three entrants in a class could expect a higher than 10% market share at two years.

In the face of this, the only effective response is speed: increased speed of clinical development to be first to market, increased speed of commercialisation to drive establishment before competitors arrive. The pandemic environment has just added further complexity on top of this challenge, slowing down and depressing uptake.

Companies must now combine speed with focus on the three pillars of post-pandemic launch excellence.

Current indications are that early pandemic launches, if they under-performed, will struggle to recover lost commercial opportunity. From now on, companies with launches must learn every lesson from the resilient pandemic launches and prepare, early and meticulously, across the three pillars to achieve post-pandemic launch excellence. The path to launch success will be extended; whilst companies must invest for the sprint, they must also prepare for a marathon.

From now on, companies with launches must learn every lesson from the resilient pandemic launches and prepare, early and meticulously, across the three pillars to achieve post-pandemic launch excellence.

Appendix

DEFINITIONS

New Active Substances (NAS)

The pandemic performance analyses include only New Active Substance launches, except for Wegovy (included because it is a major US launch in a new therapy area). A NAS launch is defined as a novel active ingredient launched in a market for the first time, with a launch being the first appearance of sales for the molecule in IQVIA's MIDAS database. It can include both single molecule as well as combined molecule products.

Orphan medicines

In the US, orphan launches are defined as molecules with at least one approved orphan designation from the FDA. In all other countries, including Japan and China, products were considered an orphan if they were designated orphans by the EMA.

Geographic scope

US, Japan, France, Germany, Italy, Spain, UK, China.

METHODOLOGY

Benchmark analyses

To assess the impact of the COVID-19 pandemic on launch performance, we used the average first six months' cumulative sales of launches and compared pandemic launches (between January 2020 and September 2021) to a relevant pre-COVID-19 benchmark.

Pre-COVID benchmarks:

- Benchmarks are the average first six months sales created for each product category (orphan, specialty non-orphan, or non-specialty) in each country. This means the benchmarks are specific to both country and product type.
- The pre-COVID-19 cohort was defined as NAS launches between April 2015 and September 2019, six months prior to when lockdowns began in most countries in scope in March 2020.
- Hep C launches are excluded from the benchmarks.
- The same methodology was repeated to calculate pre-COVID-19 benchmarks for cumulative 15 month sales.

Innovation follows a historically consistent mix

- Most launches are entering the same types of therapy area – oncology, immunology, and rare diseases- as before the pandemic, and the unmet need in these areas remains high. Around one third of innovative launches in our country scope are in oncology both pre- and post-pandemic (30% pre-pandemic versus 34% post-pandemic), as well as a similar proportion of innovative launches in immunology (7% pre-COVID-19 versus 6% post-COVID-19).
- A large proportion of innovation in both the US and Europe continues to be orphan medicines, which in Europe, must be in areas where there is no satisfactory treatment, or offer a significant benefit beyond what is already available.[30] Low patient numbers for orphan medicines does not necessarily equate to low commercial potential; in fact, the best performing European launches by our measurement of first six months sales at list prices (excluding rebates and discounts) are orphan products (Zolgensma and Trikafta).

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