White Paper

Launch Excellence VIII

The challenge of change: building Excellent launches in the post-pandemic environment

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Introduction

Welcome to the eighth edition of IQVIA's Launch Excellence series, published bi-annually since 2007. We've reached this milestone because the launch environment is in a state of continuous evolution, with both internal drivers (what is launched, with the increasing focus on specialty and rare) and external ones (health system, access, customer engagement environment). Environmental evolution was combined with a trend break from 2020 onwards due to systemic changes in healthcare provision, healthcare professional engagement by pharmaceutical companies, and healthcare budgets triggered by the COVID-19 pandemic. More than three years after the pandemic started, these forces still shape the launch environment, with consequences for which launches are most successful ("Excellent") and the activities that create them.

The core eight countries for global launch success, contributing some 90% of cumulative first five years of New Active Substance (NAS) sales are the US, Germany, Japan, China, France, Italy, UK and Spain. The US is by far the most important, typically seeing first launch and contributing over half of cumulative first five years sales. Launch Excellence as we define it is a rare achievement across these countries; for the pandemic, or post-pandemic cohort launched since Q4 2019, only 6% of specialty care and 1% of primary care launches were Excellent across two or more countries. Pharmaceutical companies are still inconsistent on launch performance country by country, and fail to realise full launch potential as a result.

In the past, shaping the environment meant shaping the commercial and opinion leader environment. Now, shaping the environment is more fundamental: healthcare systems remain fragile and under-resourced, and the launches entering them are often increasingly sophisticated in terms of their demands on healthcare systems, for example, the complex logistics that are required to administer cell or gene therapies, or the growth in companion diagnostics for an increasing number of oncology launches. A gap is growing between the healthcare system preparation needs of a growing group of launches and the ability of healthcare systems to meet those needs, exacerbated by the damage done to health system capacity by the pandemic. Addressing this gap to bring sophisticated innovation into health systems in an effective and sustainable way will be the new focus for future Launch Excellence.

Since Q4 2019, only 6% of specialty care and 1% of primary care launches were excellent across two or more countries.

Post-pandemic launch environment: are we recovering?

Environmental challenges add incremental pressure on post-pandemic launches

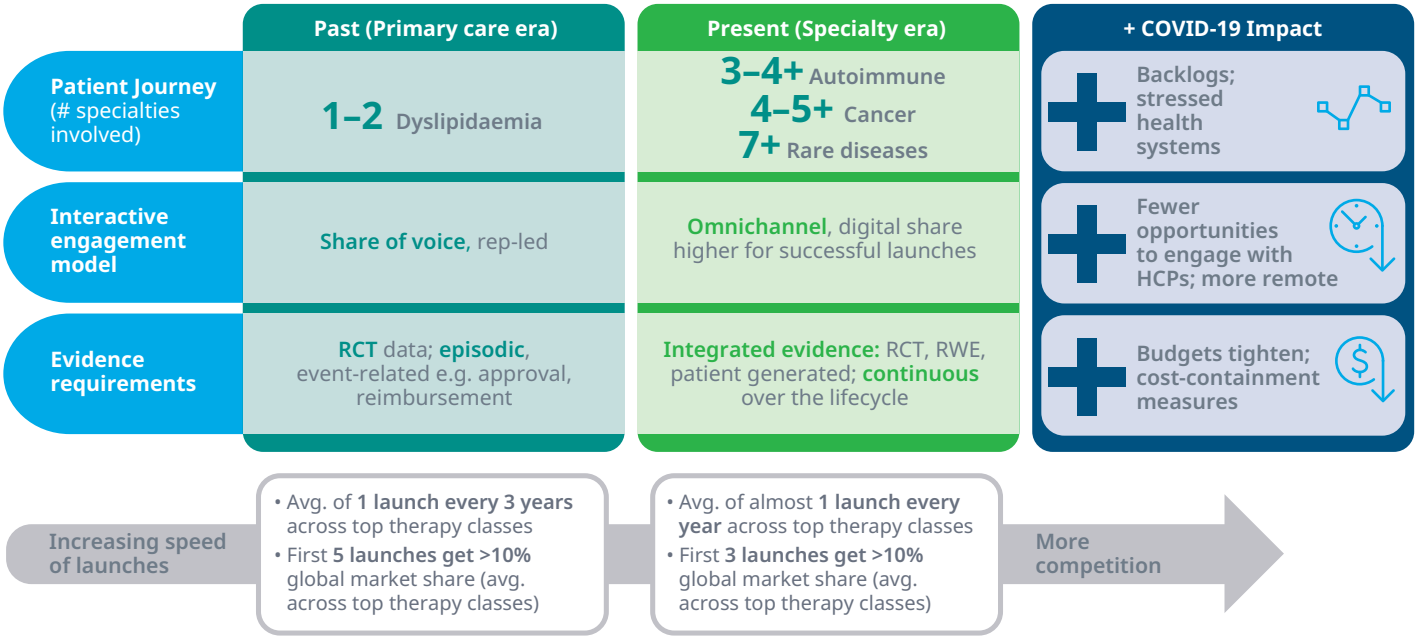
The launch environment was increasingly challenging prior to the pandemic, with predominantly specialty launches bringing a more complex patient journey, and the promotional and evidence environments becoming more multi-factorial. These trends accompany an increase in the overall number of launches into major therapy areas, a decrease in the interval between new launches and a decrease in the number of launches holding more than 10% global share of a therapy market after 2 years. The launches of the past three years face additional pandemic precipitated challenges:

1. Fragile health systems and more complex, leakier patient journeys to diagnosis and launch use
2. Reduced and altered interactive engagement between pharmaceutical companies and healthcare professionals
3. Tightened budgets with raised access barriers

IQVIA previously identified three areas for incremental launch focus as the "Three pillars of Post-Pandemic Launch Excellence" as discussed in our 2022 white paper.[1] These pillars continue, but also evolve.

The launch environment was increasingly challenging prior to the pandemic, with predominantly specialty launches bringing a more complex patient journey, and the promotional and evidence environments becoming more multi-factorial.

Figure 1: The COVID-19 pandemic has added incremental pressure on launches



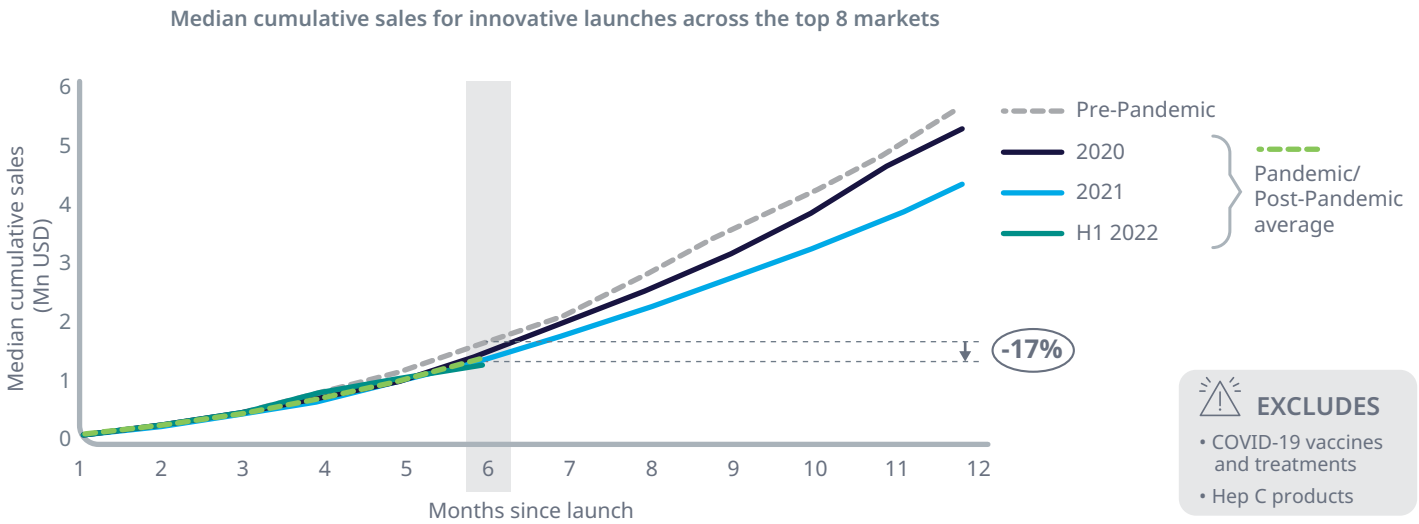
Source: IQVIA EMEA Thought Leadership.

Median post-pandemic launch trajectories still track below historic levels

More than three years since the COVID-19 pandemic began, median sales in the latest cohort of H1 2022 innovative launches across the top eight markets are still 23% below historic levels for the first six months, and across all cohorts are 17% down (Figure 2). Worryingly, the median sales trajectory is decreasing: cumulative sales for the first six-months were 10% below pre-pandemic levels for the launches of 2020, 18% below pre-pandemic levels for the launches of 2021 and 23% below pre-pandemic levels for the launches in the first half of 2022.

Executing a new launch at a time when health systems were intensely occupied was difficult. It is also likely that preparing for a launch at a time of high distraction and uncertainty presented similar challenges, and the launches of 2021, 2022 and beyond had a sub-optimal pre-launch preparation period. Improving launch preparation by focusing on the triple pandemic challenge of patient and healthcare system impact, healthcare professional engagement and budgetary challenge is key.

Figure 2: Performance of innovative launches pre-COVID-19 versus post-COVID-19



Source: IQVIA EMEA Thought Leadership, IQVIA MIDAS Monthly 2023 (accessed April 2023).
Notes: Rx only; USD in CER; Pre-pandemic launches: Q2 2016 to 2019; Includes NAS launches as well as other launches considered to be significantly innovative (e.g. non-NAS launches in a new therapy area, orphan disease or new combinations including an innovative branded medicine); Excludes Hep C products, COVID-19 Vaccines and Treatments; Countries included are US, China, Japan, UK, Germany, Italy, France, Spain.

More than three years since the COVID-19 pandemic began, median sales in the latest cohort of H1 2022 innovative launches across the top eight markets are still 23% below historic levels for the first six months, and across all cohorts are 17% down.

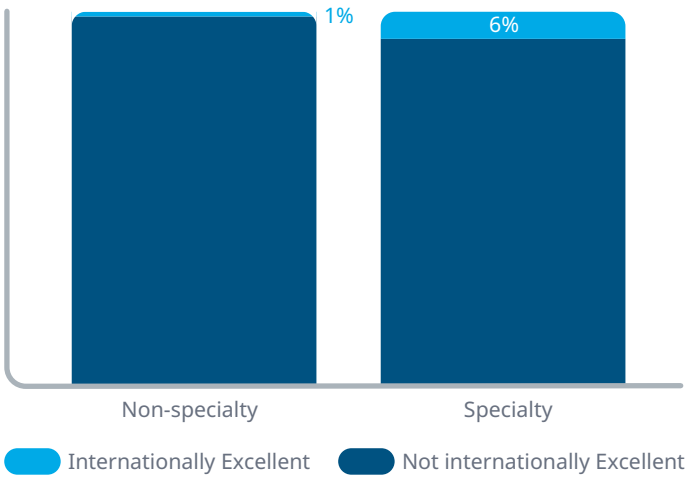
Launch fundamentals: have they changed?

Our Launch Excellence methodology has remained similar over 16 years; establishing, for a cohort of launches, what is typical launch commercial performance in a country and then identifying what is exceptional performance relative to that. Inevitably, the methodology has evolved as data provision and analytic methodology have, and Launch Excellence VIII is no exception, as the pandemic caused a significant trend break. More information about the steps we took to reflect this can be found in the methodology section of the appendix.

Specialty products are more likely to be successful globally; there is a new type of primary care which is patchy and circumstantial

For post-pandemic launches, we found that 6% of specialty products are internationally Excellent, and only 1% of primary care products are internationally Excellent (Figure 3). This is consistent with our recent Launch Excellence studies which also found that specialty products have a higher likelihood of international Launch Excellence than non-specialty products; however, non-specialty launches are less likely to be internationally Excellent than in the past.

Figure 3: Pandemic/post-pandemic — share of internationally Excellent launches



Source: IQVIA EMEA Thought Leadership, IQVIA MIDAS Monthly 2023 (accessed April 2023).
Notes: Includes innovative launches from Q4 2019 –H1 2021 where the first six months sales may be impacted by the pandemic; Excludes orphans, Hep C products, COVID-19 Vaccines and Treatments; Countries included are US, China, Japan, UK, Germany, Italy, France, Spain.

Across all launches (pre and post-pandemic) more than half (54%) of the specialty products which are Excellent in any country are also Excellent in at least one other, but almost all (92%) of primary care products that are Excellent in any country are only Excellent in one country. There have been some extremely successful primary care launches in the latest cohort — in fact, many of the top post-pandemic launches in the US across any category are in primary care areas, such as diabetes (Mounjaro), obesity (Wegovy) and migraine (e.g. Nurtec, Ubrelvy). However, primary care success in the latest cohort has been US focused.

One factor is that this new wave of successful US primary care launches for migraine and obesity had not yet launched in Europe at our cut-off (H1 2022 launches followed to the end of December 2022, although some such as Vydura/Nurtec and Wegovy have launched in Europe since). These launches have been slower to roll out in Europe than is typical, in some cases partly due to supply issues. US success for these consumer-driven launches has happened in an environment of Direct to Consumer advertising and patient assistance programs which reduce or eliminate patient out-of-pocket costs.

85% of internationally Excellent launches are in just three specialty therapy areas

We also explored the therapy areas where international Launch Excellence does exist and found that 85% of the internationally Excellent launches are concentrated in three specialty areas: Oncology (44%), HIV (26%) and immunology (15%) — note we excluded the Hep C launches from our analysis due to their unique uptake pattern. In Launch Excellence VI, when we split specialty and primary for the first time for launches from 2010 and 2016, the split of internationally Excellent launches was 51% specialty to 49% primary care.[2] Specialty dominance of Excellent launches has therefore increased.

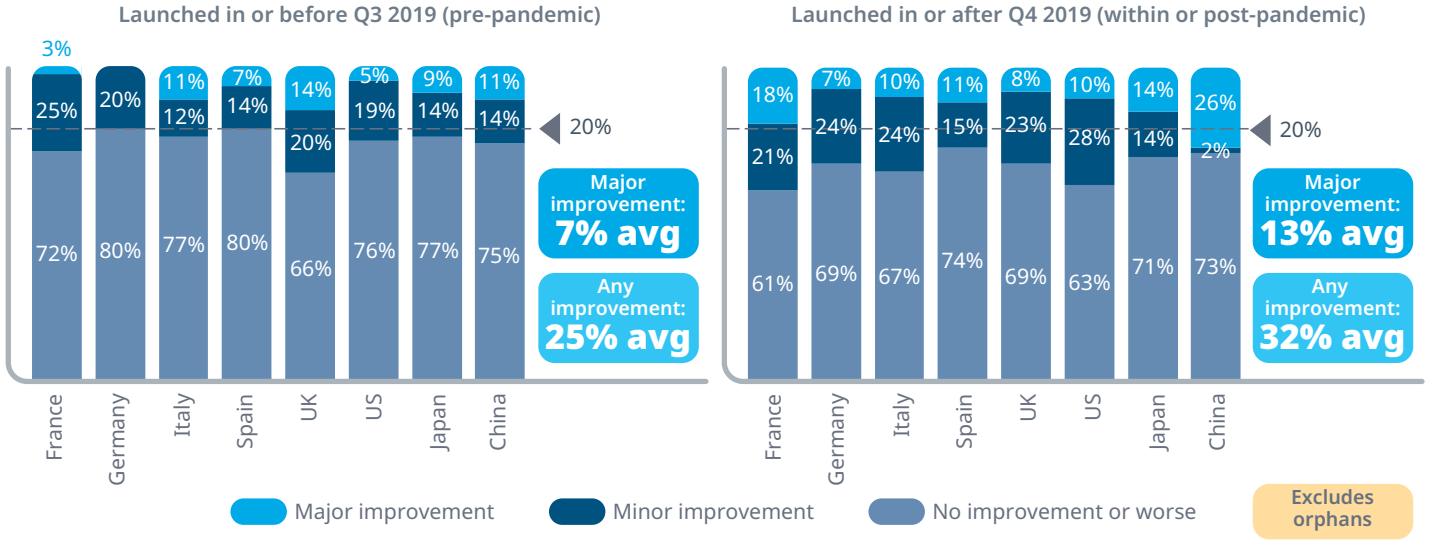
The 6-month window still holds true, but more post-pandemic launches show improvements between 6 and 18 months

Since the very first Launch Excellence study, we have found that the first six months of launch is a critical time period which determines the long-term success of more than 80% of launches. This means that if a launch has a poor start, only 20% or fewer launches are able to significantly improve their launch trajectory and change their fate, reflecting the critical importance of the pre-launch phase and rigorous launch planning.

For this year's analysis, we looked at the products which launched within or post-pandemic separately to determine if this rule holds true in a period when, launch trajectories were, on average, reduced and complicated by environmental challenges. We found that in all cases, except in China, the 80:20 rule was not breached. The first six months remains a vitally important time frame for new launches. However, crucially for launches which had a poor start due to the pandemic, we also see that more launches are improving their trajectory beyond 6 months compared to pre-pandemic. Specifically, the average proportion of launches that significantly improved their trajectory between 6 and 18 months across the top eight markets was 7% pre-pandemic versus 13% post-pandemic (Figure 4). Moreover, if we look at the proportion of launches that are improving their trajectory at all — we find that around one quarter of launches were able to improve their trajectory pre-pandemic compared to almost one third of launches post-pandemic. This is good news for the launches of 2020 and 2021 which started poorly, as more launches compared to historic levels are indeed improving their trajectory, albeit by modest levels.

The first six months remains a vitally important time frame for new launches.

Figure 4: The six-month window holds true, but more pandemic/post-pandemic launches show improvements between 6 and 18 months versus pre-pandemic



Source: IQVIA EMEA Thought Leadership, IQVIA MIDAS Monthly 2023 (accessed April 2023).
Notes: USD in CER; Pre-pandemic launches are launches where the first 6-months sales in a country are before COVID (Q2 2016 to Q3 2019); Post-pandemic launches are launches where the first six month sales may be influenced by the pandemic (Q4 2019 – Q2 2021); Includes NAS launches as well as other launches considered to be significantly innovative (e.g. non-NAS launches in a new therapy area or new combinations including an innovative branded medicine); Excludes Orphans, Hep C Products, COVID-19 Vaccines and Treatments.

Most products that significantly improve their trajectory between 6 and 18 months are specialty

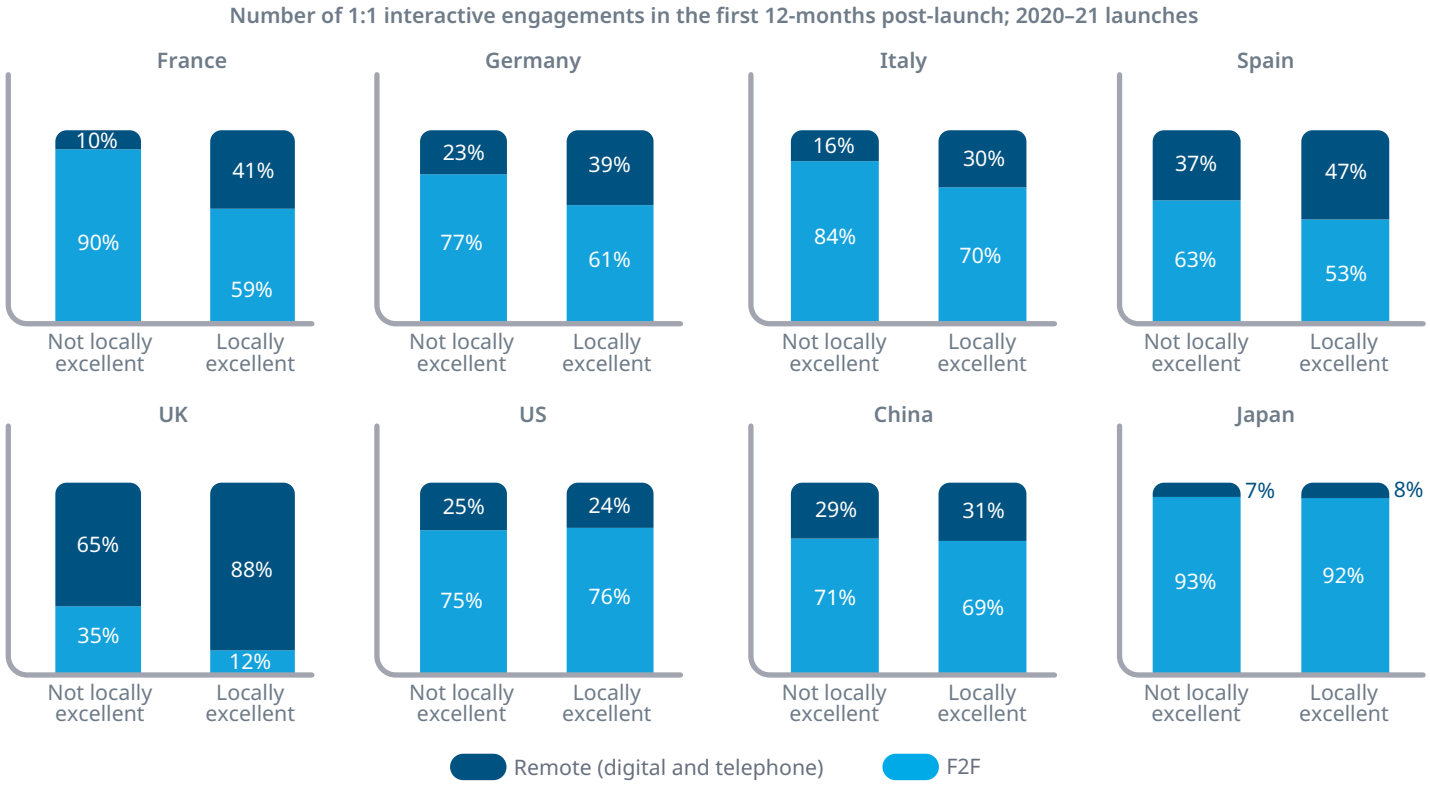
We investigated the products that significantly improved their trajectory between 6 and 18 months to understand the patterns and types of products most likely to improve. The majority of these products are specialty (~70%), with the top therapy areas being Oncology (~23%, specialty), Immunology (13%, specialty) and Anti-diabetics (~12%, non-specialty). This reflects that fact that the number of specialty launches far outweighs the number of primary care launches in today's environment — in fact, a similar percentage of launches significantly improve their trajectory when expressed as a proportion of the number of launches in their segment (~9% for non-specialty and 10% for specialty).

However, there are apparent differences in the pattern across countries. In EU4/UK, the majority of products significantly improving their trajectory are specialty (85%+) in most countries. Outside of Europe, this looks different- a segment of non-specialty launches are significantly improving their trajectory between 6 and 18 months.

Excellent launches have a greater share of remote interactive engagements in Europe

Post-pandemic, Excellent launches have a greater share of remote interactive engagements across Europe (Figure 5). Whilst post-pandemic sample sizes are small across all countries, we also observed that the more commercially successful launches were also the more digital launches even before the pandemic.[3]

Figure 5: Channel mix for Excellent pandemic/post-pandemic launches versus others



Source: IQVIA EMEA Thought; IQVIA ChannelDynamics, May 2023.
Notes: 1:1 detailing only; Remote includes digital and telephone; Locally excellent launches identified as per IQVIA TL Launch Excellence Methodology.

Outside of Europe, differences in channel mix between Excellent and non-Excellent launches are minimal. Further analysis indicates why: outside of Europe, and particularly in the US, Excellent launches had so many more interactions (on average) versus non-Excellent launches that this is likely the dominant factor of success rather than channel mix (Figure 9). Conversely, differences in the number of interactive engagements between locally Excellent and locally non-Excellent launches in European countries were generally more modest.

IQVIA ChannelDynamics™ data shows that across all products there has been a greater reduction in overall interactive engagements in the EU4 and UK versus the US, China and Japan. According to the latest data in April 2023, France, Germany, Italy and the UK still have more than one third fewer interactive engagements with HCPs versus pre-pandemic, and that figure is -23% in Spain (compared to +7% in the US, -11% in China and -22% in Japan).[4] Greater restriction to HCPs in Europe means that channel mix seems to be particularly important for Excellence in Europe, possibly out of necessity.

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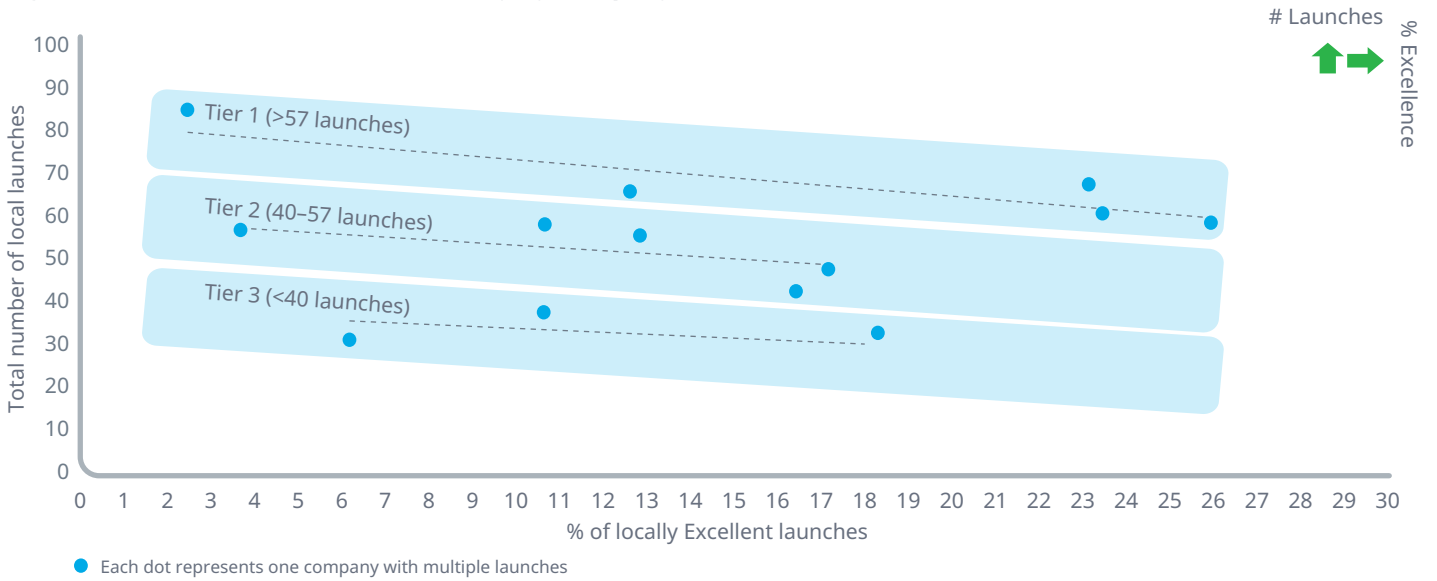
Focus (on products or disease areas) is key

Launch Excellence is a multi-factorial and consistent challenge: even well-resourced and experienced companies struggle to deliver consistent Excellence across launches. In previous Launch Excellence studies, we identified an inverse relationship between the number of launches that a company had in a given time period and the proportion that were Excellent, suggesting that the complexity of multiple launches outweighs the potential advantages of a greater level of experience. Similar to LEVII, we find that within tiers (segmented by number of launches), this is still the case for the top pharma companies (Figure 6).

Figure 6: Launch Excellence consistency by company



Source: IQVIA EMEA Thought Leadership analysis; IQVIA MIDAS monthly, April 2023.
Notes: Top 15 pharma companies by sales in Q4 2022, excluding two companies which had no Excellent launches in this cohort; Includes innovative launches between Q2 2016–H1 2021 across top 8 markets (NAS launches as well as other launches considered to be significantly innovative such as non-NAS launches in a new therapy area or new combinations including an innovative branded medicine); Number of launches includes orphans and Hep C products, but neither Hep C or orphans are analyzed for Excellence; Excludes COVID-19 products.

We also observe that companies focused on launches in a small number of disease areas are likely to have a strong proportion of Excellent launches: the three companies where launches were focused in the fewest therapy areas (4 TAs) all have >15% of Excellent launches. This does not mean that diversified companies cannot or do not achieve great success, but it does suggest that achieving launch success is easier with greater focus. Ultimately, striving to achieve Launch Excellence, and doing so across multiple launches, therapy areas and ATC3 classes is clearly a worthy goal.

The companies which lie in the top right quadrant (with both a high number of launches in the latest cohort, and a high proportion of Excellent ones), often have portfolios dominated by the therapy areas that we saw dominated specialty international Launch Excellence — oncology or HIV. Moreover, these companies also often had products with characteristics of resilient post-pandemic launches that we discussed in our last white paper.[5] These are products which reduced the healthcare burden (decreasing hospital visits or via rapid/at-home administration), and/or products where there is still high motivation to treat, such as areas of oncology where there is a high unmet need. These characteristics meant that products with these features often did well across many countries during the pandemic.

Companies focused on launches in a small number of disease areas are likely to have a strong proportion of excellent launches.

Trends shaping future Launch Excellence

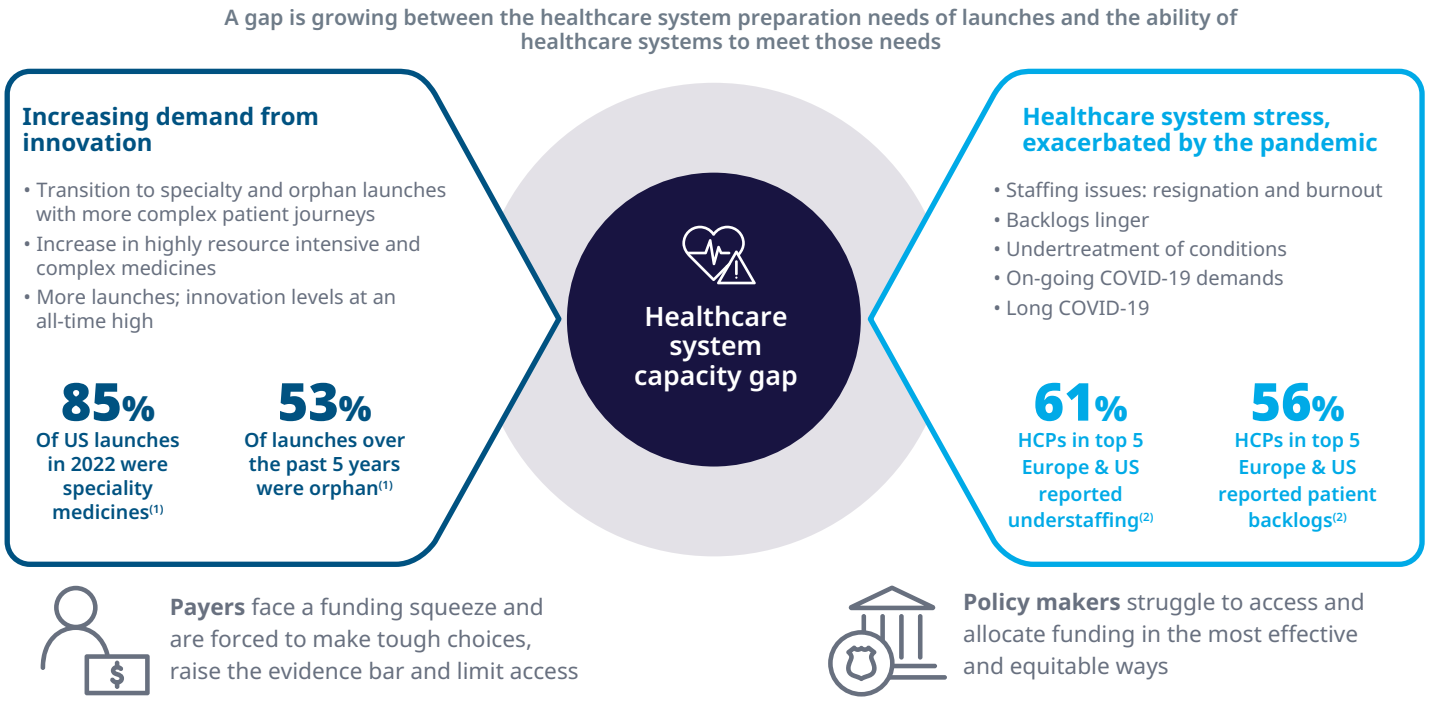
There is a growing gap between the demands of new innovation and healthcare system capacity

Healthcare systems responded to the pandemic crisis in many exceptional ways, mobilising unprecedented resources and coping with change as never before. However, capacity is squeezed from all angles, compromising the ability of health systems to prepare for and utilise launches optimally.

Transition to more specialty and orphan launches grows demands on healthcare systems; products are often more expensive upfront, they may require use of companion diagnostics and need special administration by trained, specialist personnel in hospitals rather than homes. The trend to increasingly sophisticated launch products will continue: the pipeline is dominated by oncology products (which demand increasingly complex biomarker testing), and rare disease medicines.[6] There are also a growing number of advanced therapies such as cell and gene therapies, which require fundamentally new operations and resources. The number of global New Active Substance (NAS) launches in the past five years is substantially higher than the five years prior, and whilst there is a dip in the number of new NAS launches in 2022[7], the pipeline is rich and we expect this to be temporary. Recent breakthroughs in the high-prevalence, chronic diseases of aging and affluence, such as Alzheimer's and Obesity bring great promise, but also both economic and health system challenges to realise that promise.

Secondly, the long aftermath of the pandemic finds healthcare systems in the lead 8 countries with long term stresses which have consequences for patients, healthcare professionals, and for launches. Staffing

Figure 7: There is a gap in health system capacity which must be addressed to allow new launches to reach their full potential



Source: IQVIA EMEA Thought Leadership; 1. IQVIA Institute, Global Trends in R&D 2023: Activity, Productivity, and Enablers 2. IQVIA Primary Research, Impact of COVID-19 on Healthcare System in EU4, UK & US, March 2023.

issues are a near-universal and fundamental challenge, with burn-out, quitting, and lack of sustainable staff replacement all serious issues called out by the WHO in their September 2022 report, and other sources.[8] IQVIA's most recent primary research with HCPs, undertaken in March 2023 in the US and top 5 Europe, saw more than half of respondents in all countries report under-staffing due to resignation and burnout, rising to 64% in the US and 74% in the UK (Figure 10). Across the US and the top five European markets, the same survey saw an average of 56% of physicians reporting patient backlogs, rising to 79% in the UK, 68% in Spain and 64% in Italy. Whilst the pipeline is full of new and exciting innovation, the environment that these products will launch into will be hindered by capacity issues which could ultimately impede launches fulfilling their full potential.

The transition to more specialty and complex medicines, and additional stress on health systems due to the pandemic are two (of many) reasons why medical affairs is an increasingly important function that can make or break a launch.[9] MSLs are well-placed for leading broader healthcare system engagement, and we will discuss why early deployment of medical resources (pre-launch where it is currently often underutilised) is important for future launch success in the recommendations.

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Stricter payer management challenges pharma's margins and shifts evidence thresholds and requirements

The pandemic also increased financial pressures, forcing payers to make tough choices, and tightly manage access to new therapies, often raising the evidence bar. In Germany, major policy changes which came into effect in early 2023 (the GKV Stabilization Act) resulted in some companies that don't believe they can achieve the right benefit rating choosing not to launch products at all, particularly in Oncology (e.g. BMS will not launch Opdualag, despite a strong US launch[10]). This reflects the rising importance to achieve an 'added benefit rating' in order to secure favourable pricing in Germany (and beyond, since Germany is a common reference country for markets using external referencing pricing). The way that the post-pandemic environment has impacted evidence requirements, and how companies should respond, is explored in more detail in IQVIA's recent white paper: Journey Into the Whirlwind; Post-COVID pricing and evidence policy changes and their implications for development and commercialization.[11]

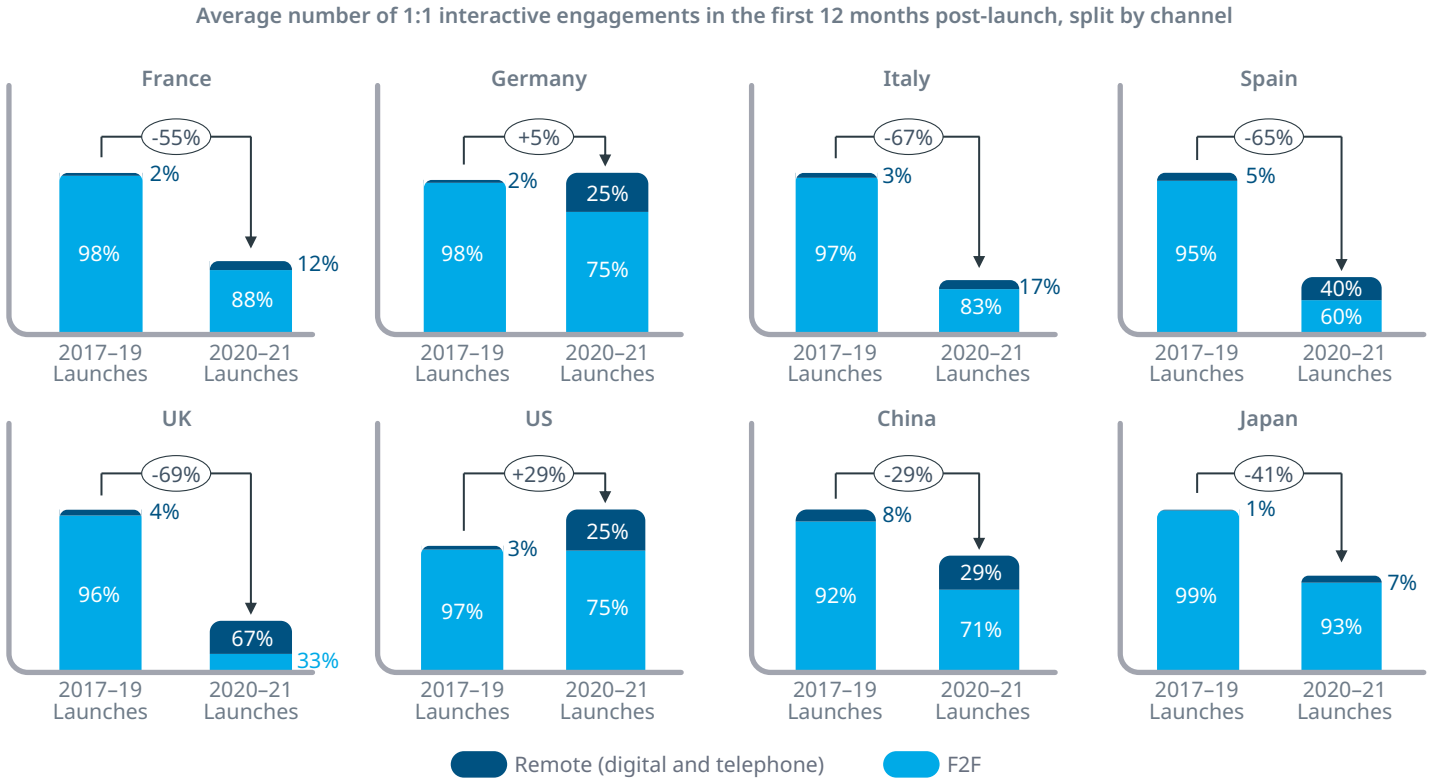
In the US, payer control of newly launched products continues to increase, and in 2021 only one in four new-to-brand patients who attempted to fill a prescription for a launch brand was successful.[12] As payer coverage declines, manufacturers are increasingly stepping in to cover the costs. IQVIA estimates that over half of total US prescriptions for newly launched brands in 2022 had full payer support from the manufacturer, up from less than 10% in 2018.[13] This high cost for access ultimately challenges launch profitability. In the UK, increasing Voluntary Scheme for Branded Medicines Pricing and Access (VPAS) rebates could also challenge pharma's margins – and an EMIG survey found that 85% of pharma respondents indicated that their companies may be likely to move one or more medicines down the launch sequence in the UK as a result.[14]

Average volume of interactive engagements for innovative launches is far below pre-pandemic levels

Interactive engagement between a pharmaceutical company behind a launch and healthcare professionals is critical to introduce the product, answer questions, collect feedback and generate awareness. Since the pandemic, IQVIA's ChannelDynamics™ audit consistently finds the number of interactive engagements (face-to-face and remote, for all products including launches) that pharma has with HCPs is down by 20–40% across the top five European markets and Japan, ~10% down in China, and only recovered (and exceeded) 2019 levels in the US. This impacts new launches the most, and our new analysis found this reduction is even more extreme when we focus only on launches, in most key countries, but this is not the case in two of the most important launch markets: the US and Germany (Figure 8).

In the US, the volume of interactive engagements has recovered and exceeds pre-pandemic levels, driven by growth in remote engagement, and launches reflect this. In Germany, recovery for launches is also driven by remote engagements; a heavy focus on specialty launches has brought with it a specialist healthcare professional audience which is more open to remote engagement. It is striking that the two countries where interactive opportunities are higher than pre-pandemic for launches see this powered by remote interactive engagement.

Figure 8: Pre- versus post-pandemic — average number of 1:1 interactive engagements per launch

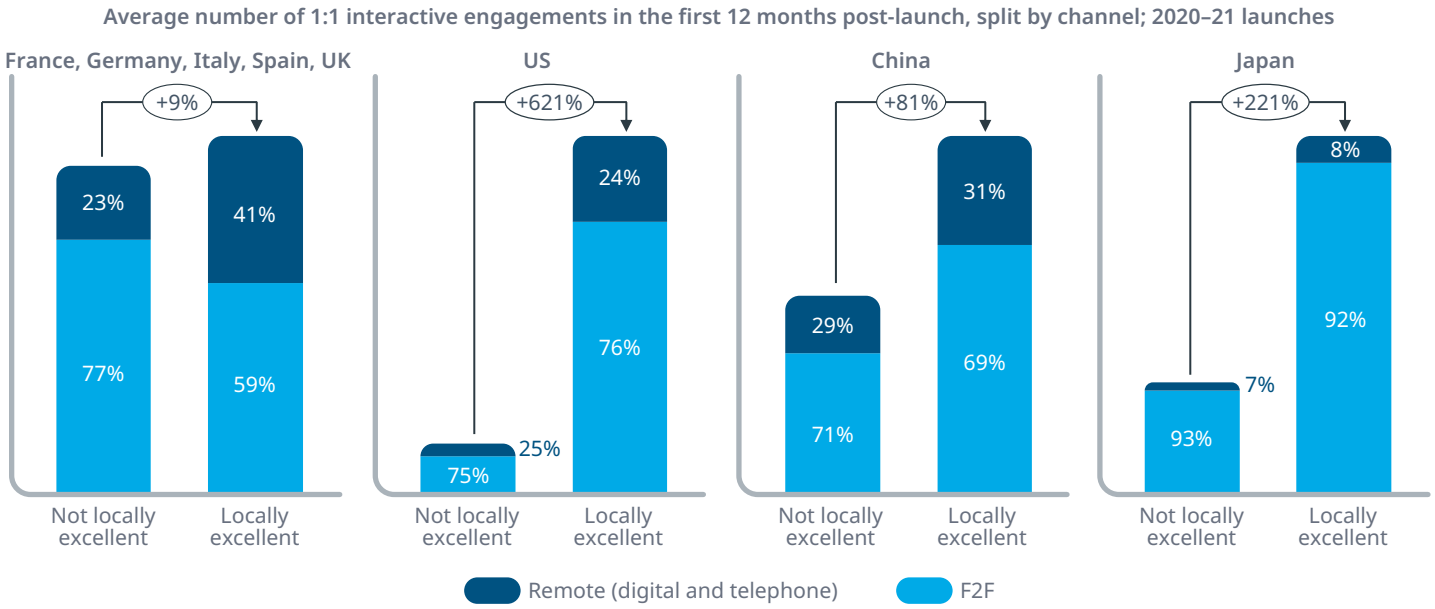


Source: IQVIA EMEA Thought Leadership; IQVIA ChannelDynamics, May 2023.
Notes: Remote includes digital and telephone; Pre-pandemic refers to launches in 2017-2019; Post-pandemic refers to 2020-2021 launches.

Excellent launches have more interactive engagement

When Excellent launches in the pandemic/post-pandemic cohort are compared to their non-Excellent counterparts, the volume of interactive engagement is higher for Excellent launches (Figure 9). The difference is most striking outside of Europe, particularly in the US. Outside Europe, face to face engagement still plays a strong role in launch and more is better. In Europe, this does not hold — face to face is important but not a clear differentiator. Mix matters.

Figure 9: Pandemic/post-pandemic Excellent launches versus others — average number of 1:1 interactive engagements per launch



Source: IQVIA EMEA Thought; IQVIA ChannelDynamics, May 2023.
Notes: 1:1 detailing only; Remote includes digital and telephone; Locally excellent launches identified as per IQVIA TL Launch Excellence Methodology.

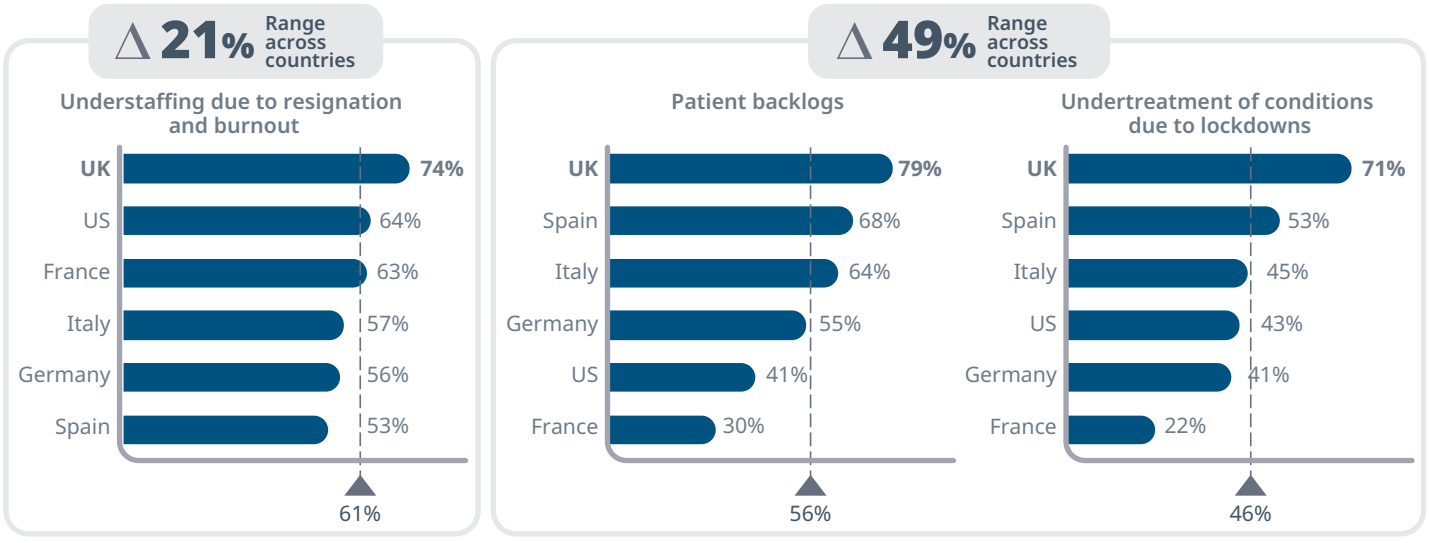
Recommendations for future Launch Excellence

The R&D pipeline is full of exciting new innovation, but IQVIA's work on launch archetypes shows that launch success is not a given even for the most revolutionary products[15], and the post-pandemic environment has created new imperatives to thrive. Therefore, we have evolved the Three Pillars of Post-Pandemic Launch Excellence to reflect what we believe are the most important foundations for launch success based on our latest findings (Figure 11).

Launch engagement has already transitioned from focusing on product characteristics (safety and efficacy) to more patient-centric outcomes, but pharma must broaden its value proposition and engagement further still to meet wider healthcare system needs. Healthcare system readiness becomes more important in an environment where systems are strained, and is particularly important for resource-intensive or disruptive products. Pharma must invest early to:

- **Develop a deep understanding of local health systems, care pathways and priorities**. This must be done early and locally. Our latest IQVIA primary research found that some post-pandemic weaknesses in health systems vary significantly across countries. For example, backlogs were reported by 79% of HCPs in the UK versus only 30% of HCPs in France (Figure 10). A deep understanding of local challenges enables effective engagement with health systems by appealing to local priorities. HCPs in the UK reported the most extensive healthcare system challenges across measures (understaffing, backlogs and undertreatment) versus other EU4 countries and the US, and in parallel, products that support the system have done especially well in the UK (for example that significantly reduce infusion burden), and products which add significant resource-burden do not. Pharma must first understand the local priorities, gaps and weak links, and adapt launch preparations accordingly.

Figure 10: Impact of the pandemic on non-COVD-19 health services; (% of HCPs reporting, n=120 per country)



Source: IQVIA EMEA Thought Leadership; IQVIA Primary Research; Impact of COIVID-19 on Healthcare systems in EU4, UK, US March 2023;
Question: What are the key impacts on non-COVID-19 health services that are still a consequence of COVID-19?

- **Facilitate care pathways, end-to-end, pre-launch to prevent bottlenecks, weaknesses and gaps in the system**. For example, there are successful examples of where pharma has supported patient care pathways, even in rare disease. Horizon created a tool to help potential patients with thyroid eye disease to "Find a TED Eye Specialist" online to simplify the patient journey and funnel potential patients to the right specialists, and combined this with award-winning multi-channel DTC campaigns since there was little awareness of the disease.[16]

- **Develop partnerships with health systems at a national and local level**. Partnerships that increase system efficiency or optimise the patient experience and outcomes can enable both pharma and health systems to achieve mutual goals of expanding access to new therapies to all eligible patients and reducing delays to treatment. For example, Boehringer Ingelheim's Angels Initiative (a public/private collaboration involving multiple stakeholders) helps hospitals across twelve countries to become 'stroke-ready' by working with doctors, nurses and ambulance crews to optimise care, diagnosis and reduce treatment delays.[17] A different partnership between BMS, Macmillan and an NHS cancer trust aims to combat the longstanding capacity challenges within the cancer workforce in the UK by developing a workforce and innovation forecasting model to predict how future innovation in cancer treatment will impact the workforce resource throughout a cancer patient's journey.[18] As a non-promotional function, medical affairs teams are well-positioned to take the lead in forming collaborations with health systems, and some companies may consider having dedicated Health Systems Engagement Managers.

- **Deploy medical resources early**. Many pharma companies are yet to capture the full potential of medical affairs, especially pre-launch. If medical resources are deployed early, they can inform strategic decisions on pre-launch issues by providing unique insights, relationships and driving internal alignment.[19] For example,
  - Providing deep insights on disease, treatment landscapes, patient care pathways, unmet needs and clinical practice to help:
    - refine the product strategy (alongside integrated brand teams)
    - shape the narrative for HTA submissions
    - design pre-launch intervention strategies to prevent bottlenecks in care pathways
  - Orchestrating integrated evidence planning across functions (R&D, market access, HEOR and commercial), ensuring that outcomes are highly relevant to patients, payers and systems
  - Advising on the design of patient support programmes (PSPs) to optimise patient experience
  - Facilitating external communications across stakeholders including payers, HTA bodies, HCPs and patients to educate on the value of new innovation (both economically and clinically)

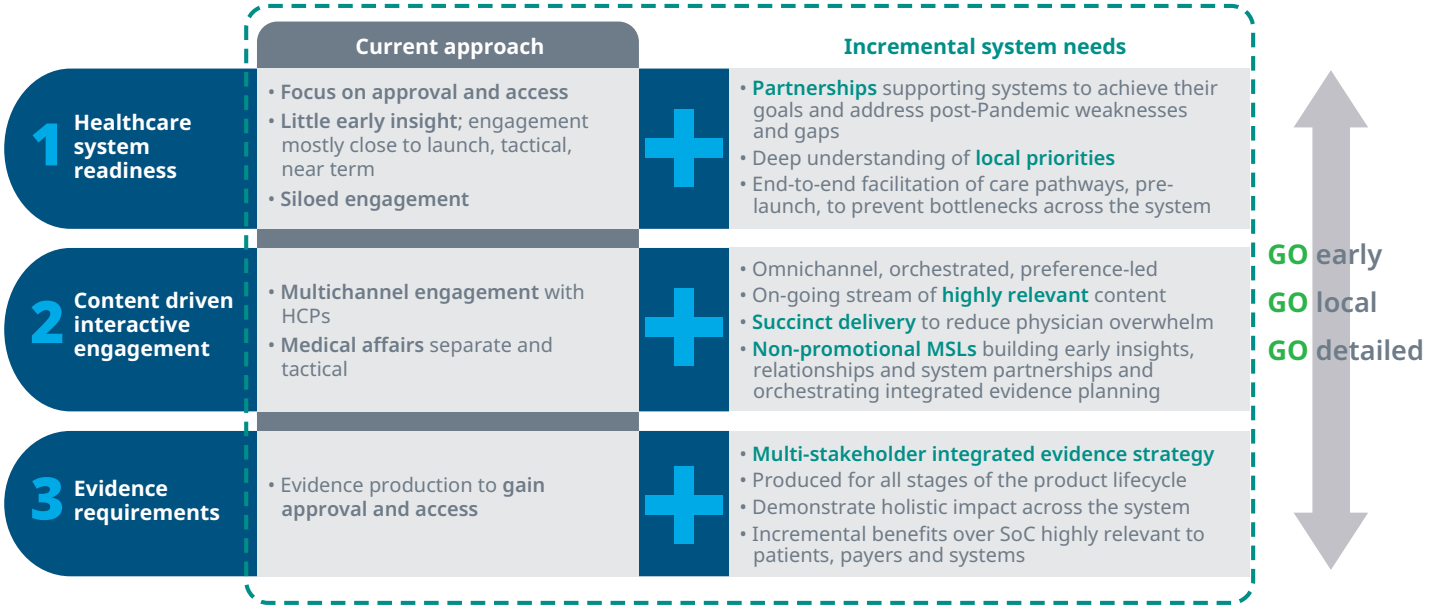
We explore how medical affairs can transform into a more pro-active and strategic role for launches, including post-launch activities in more detail in recent white papers ("Their Finest Hour: Medical Affairs in a Disrupted World[20]", and "In the thick of it: Medical Affairs, strategic partner to other functions[21]").

Many pharma companies are yet to capture the full potential of medical affairs, especially pre-launch. If medical resources are deployed early, they can inform strategic decisions on pre-launch issues by providing unique insights, relationships and driving internal alignment.

- **Develop a multi-stakeholder integrated evidence strategy to provide continuous and highly relevant evidence**. The trend to higher evidence thresholds for approval and access will increase, elevating the importance of selecting of the right comparator, patient populations and meaningful endpoints. However, in addition, the need for highly-relevant integrated evidence, including real-world evidence is increased to address post-pandemic challenges such as the funding squeeze, reduction in HCP engagement and knowledge gaps. For example,
  - Quantifying the value new innovation will bring to health systems, patients and HCPs (including the time and costs it may prevent, particularly important for transformative therapies)
  - Addressing knowledge gaps such as the impact of managing patients more remotely or patients with long-COVID. IQVIA primary research, conducted in June 2023, found that remote interactions between oncology specialists and their patients are still up on average five fold compared to pre-pandemic norms across the US, EU4 and UK[22]
  - Providing a compelling trigger for high-value HCP interactions.
- **Rebuild HCP interactive engagements and make every interaction count**: Generating new evidence throughout the product lifecycle can create opportunities to engage HCPs and help to rebuild the fall in interactive engagements. In an environment where accessing HCPs has never been more difficult, every opportunity counts more, and interactions must be carefully orchestrated, preference-led and based on highly-relevant content. Pharma must ensure that interactions deliver value to HCPs, but also a great experience.

Generating new evidence throughout the product lifecycle can create opportunities to engage HCPs and help to rebuild the fall in interactive engagements.

Figure 11: Launch Excellence means extending preparation scope to meet wider system needs



Source: IQVIA EMEA Thought Leadership.

Closing thoughts

The future for innovative launch contains considerable risk, and some certainties. One key certainty is a continued strong pipeline of innovation coming to launch: the IQVIA Institute estimates an average of 50–55 new launches in the US a year to 2027.[23] Risks include environmental changes in regions where innovative launches make the majority of their sales, which could impact the launch environment. In the US, the Inflation Reduction Act could, according to some commentators, reduce the number of innovative launches by constraining profits and therefore investment. In the European Union, the proposed reform of EU pharmaceutical legislation includes proposals encouraging roll-out of some launches across all 27 member states within two years — something that has not yet been achieved by any launch. The impact of these proposals on the launch environment in the US and Europe will be uncertain for some time: what's immediately apparent, though, is there is no regional alternative to these two cornerstones of global launch: China, whilst demonstrating exceptional growth at the topline remains very challenging for price and profitability, Japan is consistently important but without potential to become substantially more important than at present and whilst there are other regions, like the Middle East, with potential, their size means they can only augment, not substitute, core launch regions.

The changes we have observed in the last three years are long-term and systemic: there is no gradual return to a pre-pandemic "normal" — instead, we are on a new path. This is the case not just because of changes brought about the by pandemic, but also because there is a growing gap between the demand made by the innovative launches coming in on the health system and the ability of health systems to meet the new demands. Looking ahead at the pipeline, health system readiness will become even more important as many launches continue to demand more. The success of new oncology launches (~38% of the pipeline[24]) will heavily depend on increasingly complex biomarkers which require new testing capabilities to be established and widely used. Cutting-edge ATMPs like cell and gene therapies, already part of a $8.1bn market[25], require highly-skilled and new capabilities, logistics and often complete reconfiguration of patient pathways. This is a multifactorial, system-wide challenge which involves budgets, logistics, staffing, care pathways, evidence collection and evaluation. Therefore, pharma companies need a system-wide response.

The Three Pillars of Post-Pandemic Launch Excellence remain at the heart of this response: companies will need to understand and facilitate the patient journey, grow back interactive engagement levels for launches and make every single interactive engagement count and address budgetary challenge via an effective and integrated evidence strategy. Ultimately, all three pillars need to be integrated into a comprehensive strategy to address the health system challenges to enable effective adoption and uptake of new launches. This likely translates to earlier local investment and engagement. Faced with a challenging environment, Launch Excellence will mean building a value proposition that meets wider system needs.

Methodology

Definitions

Innovative launches
Our analyses are focused on innovative launches. This includes New Active Substance (NAS) launches, defined as a novel active ingredient launched in a market for the first time, as well as other launches considered to be significantly innovative (e.g. non-NAS launches in a new therapy area, orphan disease or new combinations including an innovative branded medicine). A launch is the first appearance of sales for the molecule in a country in IQVIA's MIDAS database.

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. This group of countries has typically accounted for over 90% of the cumulative first five year sales of NAS launches.

Launch Excellence Methodology
Launch Excellence VIII sees some amendments to the Excellence methodology to account for the challenging post-pandemic environment and find the launches that did excellently within these circumstances. We consider a launch to be Excellent if it outperforms within its country and cohort across three criteria (detailed below) and products which are Excellent across two or more countries are considered internationally Excellent. This year, the cohorts changed from being launches within a country and product segment (primary or specialty), to products within a country and environment (pre- or within/post-pandemic). Whilst the product category is certainly still important, the vast majority of the launches in recent years are specialty products, and specialty-type products are entering previously primary-care areas and blurring the lines (for example, Tezspire for severe asthma, Leqvio to lower cholesterol and Vyepti, an IV treatment for migraine prevention). Therefore, we compared launches within a country and environment to find the Excellent launches.

Time periods:
- **Pre-pandemic cohort**: Products that launched and had their first 6 months sales prior to the lockdowns in the majority of countries in scope (launches from Q2 2016–Q3 2019)
- **Within or post-pandemic cohort**: Launches from Q4 2019 onwards, where the first 6-months sales are impacted by the pandemic

Launch Excellence Criteria:
Launch Excellence analyses focus exclusively on non-orphan launches. As in previous iterations of Launch Excellence, a launch had to meet all three criteria within a country to be considered "Locally Excellent", while "Globally Excellent" launches were locally excellent in at least 2 countries. The 3 criteria are:

1. **Sustained sales leadership**: Sales for M9-M18 post-launch must be more than or equal to 1 standard deviation above the median (within the country and cohort)
2. **Steep launch trajectory**: Launches were ranked by cumulative monthly sales (within a country and cohort) in M6 and M18 and deciled according to rank. Excellent products must have jumped up one or more deciles between M6 and M18, or remained consistently within the top 2 deciles.
3. **Competitive intensity**: The indexed value indicating competitive intensity must be in the top 25%, specifically:

Methodology *continued*

- Launches were categorised into markets based on ATC3/4
- ChannelDynamics™ was used to determine the number of promoted products within each market at latest date (excluding products with promotional spend of less than $100k in 2022)
- Launches were then ranked (within country and cohort) based on cumulative M18 sales
- This raking was normalised to the number of promoted competitors and a launch was considered Excellent if the indexed value ranked in the top 25%

There is an important consideration: since we can only look at 1.75 years of launches post-pandemic (and follow them for 18 months), to be internationally Excellent the product must be launched, and Excellent, in two or more countries within 1.75 years. This is different to the pre-COVID where a product needs to be launched and Excellent in two or more countries within 3.5 years.

Exclusions

- **Hep C products**: Due to unique launch trajectories
- **COVID-19 products**: Due to unique launch trajectories and alternative distribution channels
- **Vaccines**: Due to alternative distribution channels

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