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Strategic Intelligence. Competitive Advantage.

THE THREE A'S OF LAUNCH READINESS

Strategizing for success

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IT CAN TAKE YEARS TO DEVELOP A DRUG

A launch can fail in a matter of weeks

Getting a drug from bench to launch takes an average of 12 years and $1.5 billion.[1] Given responsible guardianship and the careful promotion to be expected at that level of investment, it should come as a surprise when any drug falls flat at launch.

But it doesn't - drug launch failures happen more frequently than pharma companies care to admit. From 2009-2017, approximately 50% of drug launches failed to meet prelaunch sales expectations. Over 25% didn't meet half their forecasted revenues.[2] Of the 0.02% of candidate drugs (I in 5000) that successfully reach the market, only a third meet first-year financial expectation.[3]

And when launches fail, the rationalizations begin: Bad luck. Bad timetables. Unforeseen complications. Unforeseeable competition. The messaging underwhelmed the target audiences. The drug costs overwhelmed the messaging. The drug overpromised, the drug underperformed.

Any and all of these may be true. But, when each case is scrutinized individually, the evidence usually points to one of three problems: the pharma brand managers and their teams did not anticipate their own overconfidence or the moves of their competitors, they did not adapt their strategies to new market conditions as they arose, or they did not align their strategy and implementation plans across functions and geographies.

Anticipate, Adapt and Align - the three A's of successful launch strategy. To understand and implement them require more than sending out an email meeting request and marking off a block of squares on a Gantt chart. It takes strategic vision, a holistic understanding of every vagary of the marketplace, and a forthright and ruthlessly honest assessment of both the product being launched and the competitive space it is meant to occupy.

[1] Clough 2014

[2] Rafael Natanek 2017

[3] Hemant Ahlawat 2014

Every launch tells a story

The stories launches tell may be similar - all have a basic narrative of the right molecule hitting the right target and helping a patient transcend a disease. That story may involve the creation of a new kind of drug, an improvement a new drug offers against the current standard of care, the taming of an unruly adverse event associated with earlier products in the same class, a price differential, or another piece of the puzzle entirely.

Marketers often lump these concepts together under the banner of the value proposition. When well executed, a value prop can be a master narrative that explains the unmet need the drug fulfils. Poorly executed value props are often created specifically for the launch, and function to bolster the strong points of a drug and elide the weaker ones. This late-stage image building would not be necessary if steps had been taken earlier in the process to Anticipate, Adapt, and Align.

The master narrative of a drug should be a product of ruthless assessment of the marketplace - and an equally ferocious self-assessment of the pharma company's internal dynamics and the drug's clinical study reports.

This deep understanding of internal and external realities is significantly more useful than a mere value proposition. It is the result of the strategic intelligence and insights that emerge with appropriate assessment. When done correctly, the internal and external narratives align, and the strongest possible story emerges. When there are gaps between the internal and external narratives, the drug is at risk of having its story defined, and derailed by, the competition.

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Launches are harder now than ever before

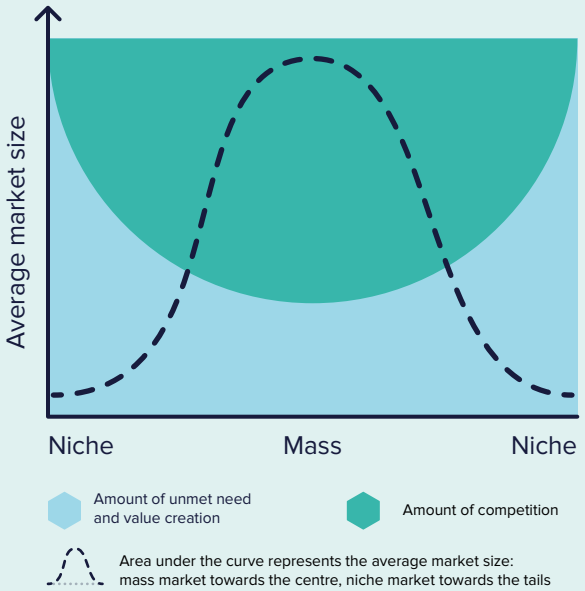
LAUNCH ENVIRONMENT OF NICHE MARKET

- High unmet needs give significant value creation, though market size maybe limited.
- Less competition results from lower number of launches.
- More recent launches have longer patent, so less pressure from genericisation and biosimilars.
- Research and development is more favoured by payors and regulators, with processes encouraging its approval and access.

LAUNCH ENVIRONMENT OF MASS MARKET

- Less unmet needs gives limited value creation.
- More competition means faster, smaller launches.
- Competition of drugs intensifies as they approach beyond patent expiry due to generic biosimilar drug launches.
- Demand of real life data and value creation from payors, insurers and regulator intensifies.

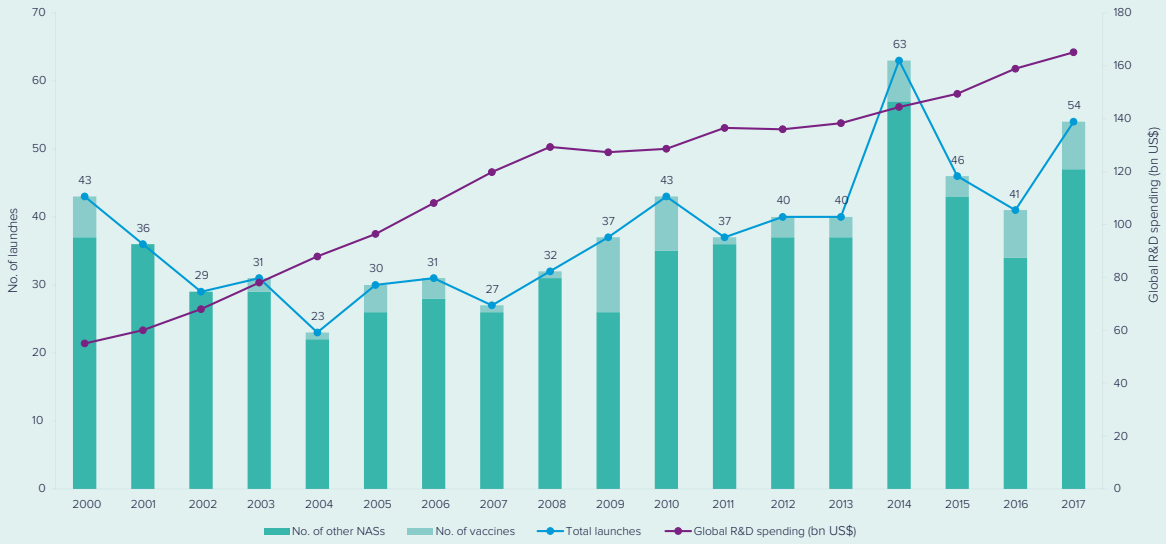
Figure 1: A general model of the current launch environment



This visual serves to capture the most common realities of mass and niche markets - it does not reflect every single situation or reality in today's dynamic marketplace.

Today, new drugs launch into a market landscape of fast-expiring patents, heavily promoted 'me-too' drugs, competitive saturation, and niche targeting. Even with all that, 2017 saw US drug approvals hit a 21-year high, the EU approved 12% more new drugs than in 2016, and China is actively working to speed up its own approval process.[4]

Figure 2: Global new active substance launches and R&D spending over time



The number of new active substances (NAS) launches and global R&D increased from 2000 to 2017.

*NAS: "New chemical or biological entities where the active ingredient had received no prior approval for human use", including vaccines with novel antigenic components; this excludes reformulated moieties, generics and biosimilars.[5]

And since the mapping of the human genome in 2003, it was hoped the discovery would lead to the finding of "the right drug for every patient."

Over time, we have seen the emphasis shift to "the right patient for every drug." [6] This narrow targeting of genetic variations in disease states may make new discoveries more difficult, but when they happen the possibility of launching "first in class" is wide open. However, the proliferation of small biotech companies fuelled by venture capital ensures that no first-in-class drug remains the only drug in its class for long.

One example: 2017 saw three different drug approvals for CDK4/6 inhibitors in first-line treatment of HR+ HER2- metastatic breast cancer. The first and second drugs to market both were approved in March of that year, the third in September. None had the luxury of defining the market on their own terms. In situations like this, where competition for a specialized niche is fierce, the need for a strategic understanding of every nuance of the market, the competition, and the values and limitations of one's own becomes even more pressing.

For every successful launch, there are a great many drugs with strong clinical trial results that have crashed and burned when put before the public. Very often, public rejection was the result of a flawed process: steps were skipped, opportunities for insightful intervention were ignored, uncritical company-culture confidence was allowed to predominate.

These and many other problems could have been reduced or rendered nonthreatening if, from the start, the pharma company had rigorously assessed the market through the lens of strategic intelligence, using the Anticipate, Adapt, and Align model.

[4] Hirschler 2018

[5] Sources:

- Pharma R&D Annual Review 2018 Supplement: New Active Substances Launched During 2017, Pharmaprojects, Pharma Intelligenc, Informa, 2018. http://info.evaluategroup.com/rs/607-YGS-364/images/WP2018.pdf
- Evaluate Pharma® World Preview 2018, Outlook to 2024. 2018. http://amife2012.pacifico-meetings.com/mailing/news10/pdf/EvaluatePharmaWorldPreview2013Outlook_to2018.pdf
- EvaluatePharma® World Preview 2013, Outlook to 2018. 2013.
- Sylwia Marshall, Joe Bedford. Therapeutic Product R&D - Market Trends. PharmTech.com. [Online] 2017 September 2017. http://www.pharmtech.com/therapeutic-product-rd-market-trends.

[6] Palmer 2013

For a more detailed analysis of the effects of this increased competition in today's pharma landscape, see our recent White Paper Disruption has hit pharma - are you ready?

However, the proliferation of small biotech companies fuelled by venture capital ensures that no first-in-class drug remains the only drug in its class for long.

The three A's

One key factor often seen in failed launches is an inability to recalculate strategies and tactics in the face of a new and unexpected market landscape. This new complication could take many forms:

- A poor awareness of competition and anticipation of competitor moves.
- An inability to adapt to changes, whether from a competitor or the market itself.
- A misalignment between global launch strategies and local realities.

Anticipate and Adapt are positioned from the view of evolving from 'Competitive Intelligence' (in blue) to 'Strategic Intelligence' (in green) from broad information (wide top of the triangle) to refined specific strategic action (point of the triangle). Alignment is required throughout the process of 'Anticipate' and 'Adapt', hence its position and the color code (purple arrow on the outer edge).

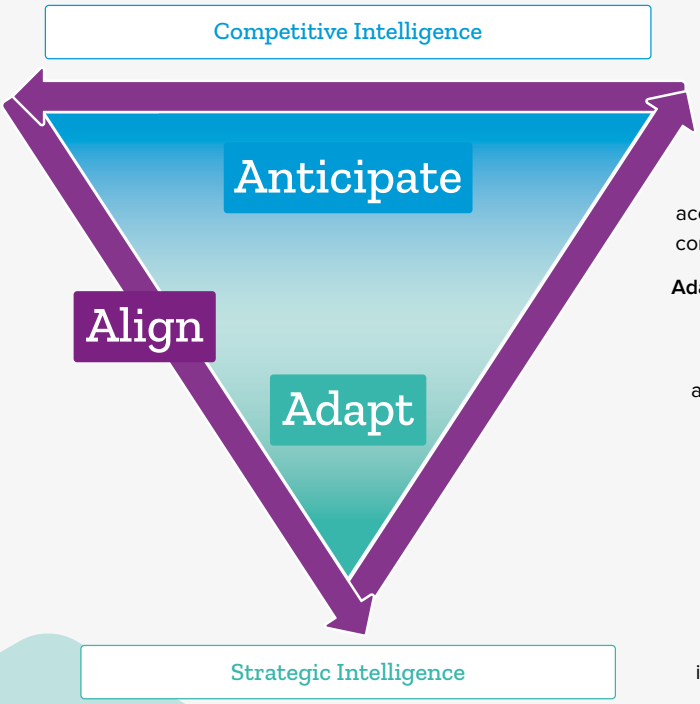
Anticipate

Anticipate competitor activity

Competitive landscape
Competitor deep dives
Scenario workshop and competitive simulation
Competitor monitoring

Anticipate stakeholder drives

Primary research with key stakeholders, including: patients, prescribers, regulators, key opinion leaders



Adapt

Adapt your launch strategies with evolving competitive response

Adapt launch strategies according to external changes via continuous competitor monitoring

Adapt your launch strategies with evolving stakeholders' needs

Adapt new marketing, market access, and customer strategies beyond traditional approach

Align

Align global planning with local realities

Facilitate communication and strategies of regional affiliates in global planning, from an early stage, i.e. Phase 2/3

Align teams cross-functionally

Facilitate communications and integrate strategies cross functions, i.e. commercial and R&D teams

The first step, **anticipate**, requires a clear vision of any and all challenges, both internal and competitive, that the pharma manufacturer may be forced to confront. Some may be likely, some far-fetched, but no solutions should be attempted until all critical, anticipatable events have been sufficiently categorized and stratified.

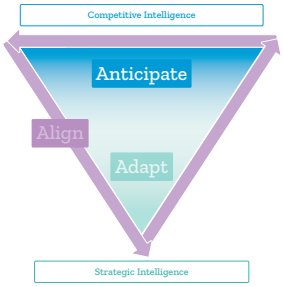
Once the most pressing anticipated problems have been considered, it may be necessary to rethink what had been fundamental assurances in the face of new information. Solutions are then considered that will **adapt** the drug's marketing strategies to overcome any perceived obstacles.

And finally, once a challenge has been uncovered and a solution proffered and found acceptable, the drug's new narrative must **align** throughout every channel, touchpoint and stakeholder who will encounter that drug. As the market is global, the alignment will necessarily be global as well - and given the complicated realities of launching drugs in different countries, the task of alignment may be no small feat.

Changes to the best-laid plans are inevitable. It is how a pharma company reacts to these changes - and how well prepared they are for every eventuality - that can make the difference between failure and success.

Anticipate

Anticipate competitor activity



Anticipate competitor activity

Competitive landscape
Competitor deep dives
Scenario workshop and competitive simulation
Competitor monitoring

Anticipate stakeholder drives

Primary and secondary research with key stakeholders, including: patients, prescribers, regulators, key opinion leaders

Competitive landscape

- Identify direct and indirect competitors in the market
- Evaluate the economic and non-economic aspects of key customers, products and company capability of the competitors
- Identify competitors' strengths and weaknesses
- Specify drug's competitive advantage and map positioning in the competitive landscape

Competitor deep dive

- Identify most relevant key competitor(s) in the market
- Continuously assess all key competitive activities
- Identify likely competitor actions and reactions to launch of drug into market
- Use competitor assessment to map potential opportunities and threats to the launch

Analyze in-depth secondary resources (SEC filings, scientific publications, clinical trial status etc.)

Secondary Research

Primary Research

Target broad range of stakeholders

Benchmarking and synthesis of findings

Generate strategies via, e.g.:
- Competitor top prioritization plan
- Market segmentation refinement
- Patient flow, leverage point analysis
- Formulation of brand vision positioning

When building a launch plan, a rigorous and probing analysis of both the competition and the drug's strengths and weaknesses is vital. The best tools to accomplish these goals are the building of a Competitive Landscape Assessment - a ruthlessly honest assessment of the launching drug and the marketspace it is intended to fill, and a deep dive into the competition the drug is likely to face.

Who are your competitors? What weaknesses, or perceived weaknesses, in your drug's data narrative could they exploit to their advantage? A thorough, meticulous dissection of your competitors' hopes, fears, and capabilities will allow you to anticipate their moves, and plan your responding strategy accordingly.

A strategically oriented competitive landscape assessment allows a pharma company to anticipate and map competitor activity and pre-empt competitor tactics. To accomplish this, in-depth assessment of every level of the organisation is vital.[7] The competitors' choices and actions in previous market challenges tell us much about their strategic planning and capabilities. Analogue studies which analyse the behaviour patterns of your competition based on relevant past situations are invaluable. Further, insights arise from consideration of their pre-launch positioning, willingness to engage in legal manoeuvring, the value proposition of their drug, what beyond-the-pill services they are planning, aggressiveness in regulatory progression, and strategies for pricing and market access.

If the process of gathering and interpreting this competitive intelligence is of sufficiently high quality, the outcome will tell a story of how competitor actions may affect your drug's future.

These outcomes serve a dual role:

- For managers charged with continuous improvement and quality control, this intelligence may expose operational flaws that otherwise would remain invisible.
- For teams directly involved with launch efforts, this intelligence, when built into the narrative of your launch plan, may afford a degree of protection that may be a critical factor for success.

[7] Hugh Courtney, Getting into your competitor's head 2009

Once enough competitor and market data has been captured, the time will come to conduct competitive simulations.

These engagements in strategic thinking are designed to put the pharma team in the mindset of their competitors and other market stakeholders, enabling them to see issues, gaps, and opportunities from other relevant perspectives. These may begin simply, as exercises in building team awareness of anticipated threats, but should over time grow in complexity across multiple launch parameters and competitive scenarios. From the start, In the competitive simulation workshops, the firm's competitors are mapped and represented by teams. Each team analyses the situation and makes key strategic decisions for their representative companies. The teams then alter their original or make counter-strategies to react to the 'market change'. Competitive simulations are usually conducted to explore a specific priority - pricing, for instance, or gaps in formulary adoption - and it may make sense to run several workshops, each devoted to specific concerns as they arise.

Many pharma executives shy away from competitive simulation due to perceived high cost and lack of clarity about feasibility.[8] In truth, the value of any competitive simulation is directly tied to the depth of knowledge built into its design.[9] A third-party specialist firm grounded in strategic intelligence can create high-value competitive simulations that will create awareness of "groupthink," enable the team to anticipate blind spots, reduce uncertainties, and build "if-then" flexibilities, resulting in a greatly reduced margin of error, and ultimately a fundamentally stronger plan going into launch.

Anticipate stakeholder needs and drivers

To get the depth of insight necessary to build an effective landscape assessment, primary research is obligatory. Key opinion leaders may offer valuable top-down views into the current realities of the market, but it is the physician specialists, nurses, patients, disease advocacy groups, payers, as well as policy makers at the institutional and governmental levels whose personal opinions and intuitions often have powerful significance.

This first-hand exploration of the experiences and needs of these active stakeholders in your drug's success may offer fewer data points than standard market research tools such as focus groups and surveys. The insights obtained, however, are often more powerful. These, combined with KOL interviews, the snapshot-like immediacy that market research offers and the deeper and longer-term study of competitor strategies, is the basis for primary competitive intelligence (CI) research. CI can be a robust driver of decision-making, and is instrumental in determining your positioning and market differentiation.

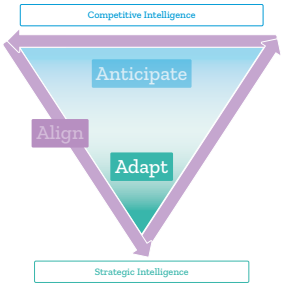
And when it comes to understanding your competitors, nothing is more useful than a first-hand look into their own thoughts and processes. Competitor intelligence, while more challenging to gather and stratify than marketing intelligence, is necessary if your aim is to fully understand what it is you are up against, and thus how you can outcompete within your market.

The value of any competitive simulation is directly tied to the depth of knowledge built into its design.

[8] Hugh Courtney, Getting into your competitor's head 2009
[9] Horn, 2011

Adapt

Because we know the ultimate goals of our competitors, we can use landscape assessment, competitive simulations, and other tools to predict their likely actions and reactions, and adapt our strategies to neutralize them. Not all market stressors, however, come from our competitors. Many forces can arise that will thwart the best-laid launch plans. Rarely are these actions entirely unpredictable, if seen from the appropriate perspective.



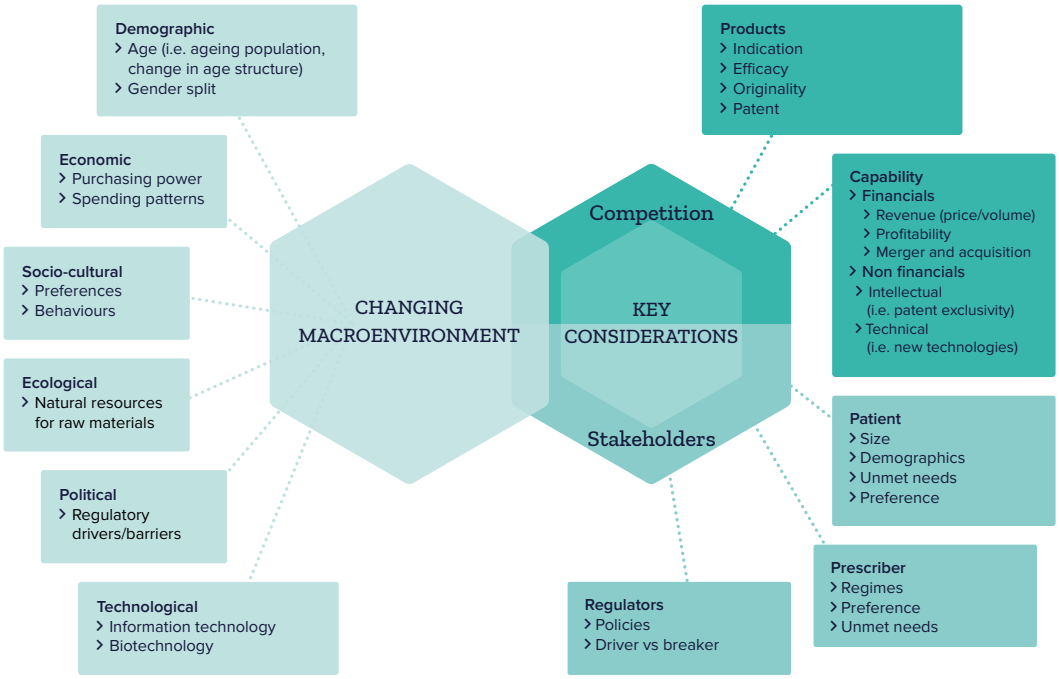
Adapt your launch strategies with evolving competitive response

Adapt launch strategies according to external changes via continuous competitor monitoring

Adapt your launch strategies with evolving stakeholders' needs

Adapt new marketing, market access, and customer strategies to those who serve as driving forces of the product

What changes or influences might affect your need to adapt your strategy?



Adapt your launch plan in the face of changing information

In any launch, a constellation of factors will always remain in flux. Consider the case of Zaltrap (aflibercept). This oncology drug launched and seemed to be making headway until three key opinion leaders published an op-ed in the New York Times that made it an example of exorbitant price coupled with unimpressive gains in efficacy versus the competition.[10]

Or consider Brilinta® (ticagrelor), tested successfully as an improvement on the ageing blood thinner Plavix (clopidogrel), at one time the world's second-highest selling drug. Plavix was facing patent expiry in May 2012; Brilinta was on schedule to receive FDA approval in late 2010, thus allowing it a year and a half to build a strong support base among doctors treating patients unable to take Plavix. But FDA concerns set the release date back 6 months, changing the fundamental mission of the launch. Brilinta's competitor was no longer Plavix, but generic Plavix. This should have necessitated a decisive change in strategy. But even in the face of this, AstraZeneca insisted on premium pricing, charging 25% more than their closest branded competitor and ignoring the fundamental change in the competitive context posed by generic Plavix. Because of this inability to adapt, the launch failed.[11]

[10] Peter B. Bach 2012

[11] Husten 2011

Hindsight, of course, is always 20/20. From the outside, Brilinta's failure may seem like it should have been obvious, but from the inside, one must assume, principles and stakeholders thought they were operating strategically. In both cases, a lack of adaptation to changing market realities doomed both launches.

Your launch must be agile enough to reconnoitre any significant challenges, expected or unlikely, with a counterstrategy determined early on and adapted to circumstances as they evolve. Primary research, competitive landscape and competitive simulation exercises are a well-established path towards accomplishing these goals. With planning and foresight, no matter what challenges you face, you will have contingencies to meet them.

Adapt your value proposition to stakeholder needs

Adaptation does not stop at countering challenges. In the US, and in many other markets as well, there is an ongoing shift of focus from the cost of a drug to the value it can bring - not just to the patient but to multiple stakeholders along the chain from bench science to bedside. These stakeholders may include the pharmacist or specialty pharmacist who stocks the drug, the nurses at the facilities where it may be administered, the patient associations and private foundations devoted to the disease state, the family members and other caregivers who help the patient through the patient journey, and many, many more. All of these are actively concerned with the value of your drug, and if their concerns are not reflected in your value proposition, don't think they won't notice.

Primary CI research into the drives of your drug's direct and indirect stakeholders - the pharmacists and nurse-practitioners as well as the patient associations and disease foundations, and even the social media associated with that patient population - can reveal nuanced motivating factors that can be adapted into your value proposition. Be assured that in this value-driven environment, your competitors are looking at the needs of these stakeholders. You have everything to gain by doing the same.

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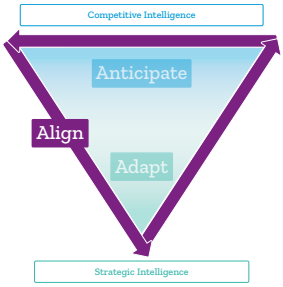
Align



Align global planning with local realities

Facilitate communication and strategies of regional affiliates in global planning, from an early stage, i.e. Phase 2/3

Align teams cross-functionally

Facilitate communications and integrate strategies cross functions, i.e. commercial and R&D teams

Set clear objectives for the cross-functional collaboration

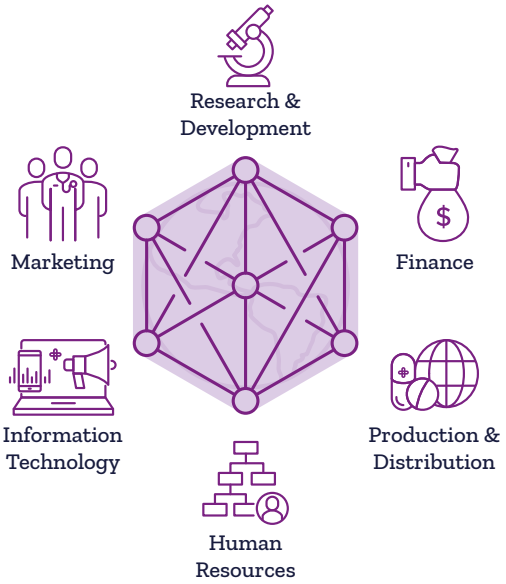
- What do we aim to achieve?
- What behaviours will achieve the desired objectives?
- What mental model will lead to the behaviours?

Communicate goals clearly, internally and externally

- Clarify the expectations within your own team and shared across different teams to eliminate assumptions

Keep the overall message/process consistent

- Standardise key vocabularies, processes and procedures



Align global planning with local realities

Pre-launch organisational alignment across regions and functions is a key differentiator of launch excellence.[12] Often a company's foreign affiliates are considered a group to be marketed to. Convention centres are booked, presentations are trotted out, individuals are wined and dined and then are sent off to perform their magic and pump their regions full of good feelings for your drug.

The problem with this? These are stakeholders in your drug's success. After all the work you've done to anticipate, adapt and align your drug to the needs of myriad stakeholders in your home country, why would you treat your foreign partners any differently?

For this reason, it is critical to align your marketing planning - up to and including your value proposition - with the needs and interests of the regional affiliates who are going to do the hard work of opening a new market for your drug.

In any global or multi-region drug launch, it is vital to have regional affiliates in the room offering their expertise during the global planning process. They know the realities on the ground in their markets. To properly align your interests, those realities must be baked into the launch planning from the start.

Align launch strategy cross-functionally

But regional affiliates are not the only stakeholders to be considered in a full alignment process. If you want your strategic plan to be put into effect as efficiently and productively as possible, alignment needs to be ensured across functional groups such as sales, marketing, medical, regulatory, market, access, policy, and more.

Optimal alignment ensures consistent and shared visions, messaging and strategic action points across all levels and functions. Different pharma companies may have different needs for alignment - horizontal, for a series of launches into countries of the EU or Asia, or vertical, for a marketing plan that considers the highly varied US market, with its range of targets from small group practices to large university hospital health systems.

Cross functional representation and alignment serves to strengthen not only the analysis, but also the network within the team itself. Cohesion and mutual understanding ensure buy-in, decrease friction and resistance, and ensure the global plan is realistic.

[12] S. R. Lisa Murch 2017

Conclusion

Staying at the forefront of the competitive curve is critical to ensure the success of a product launch. Action-oriented strategic intelligence integrates insights from customers, competitors, other stakeholders and the market environment. Strategic intelligence enables foresight into the changing pharma dynamics in the internal and external environment, and the associated changing behaviours and needs in the customers, stakeholders, and competitors.

Ask yourself:

- Is your company doing everything they can to anticipate, align and adapt their drug's entry into the marketplace?
- Have you factored in value for every ally your drug will need? Your patients may be stakeholders - but what about your customers? How does your drug make their jobs easier?
- Do you know your competition's value proposition as well as you know your own? Or are there blind spots in your company's vision of the competitive environment?
- Are you as well-protected as you think, or are there any loose threads in your narrative that can be ripped open and exposed to the world?
- Would a fearless holistic and objective assessment of the market space, and your place in it, be worthwhile?
- Is there any situation where it would not be?

By building on the framework of **anticipating** problems, **adapting** tactics to solve them, and **aligning** strategies to bring those solutions into the market, pharma companies will be better able to navigate their drugs from investigational molecules, through the complexities of approval, into the competitive national and global arena, and ultimately to the status of trusted, highly regarded and profitable staples that improve the lives of people all over the world.

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About the Author

Jesper Nissen is a Deallus consultant who has led a wide range of projects over his 5 year career at Deallus. He offers extensive experience in competitive landscape monitoring, manufacturing and diagnostics technology assessments, and global positioning and brand planning projects. His expertise covers several therapy areas including oncology, respiratory, rheumatology and rare diseases. Additionally, Jesper is leading internal and external training activities including engagements on Competitive Readiness best practices within the pharmaceutical industry.

Prior to joining Deallus, Jesper served as COO, head of strategy and BD, and member of the board of directors in a technology start-up in Cambridge, UK. He has extensive experience in the process of building a strong evidence base from which to derive the key implications and actionable recommendations necessary to any strategic decision-making process.

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