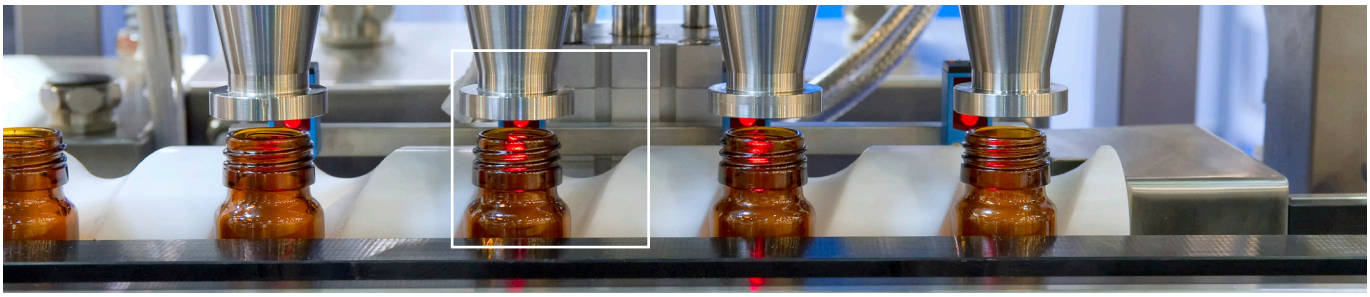
# Launch excellence for new medicines

*Global market access challenge requires new approach*



After years of low productivity, R&D in leading pharmaceutical and biotech companies is starting to deliver on its promises. The number of New Molecular Entities (NMEs) approved by the US FDA has leveled out and valuations of biotech companies have reached record levels. Now that approval has been gained, there needs to be a launch; however complexity of global market access has substantially increased. In this viewpoint, Arthur D. Little assesses the key success factors for launch excellence in times of global market access challenge.

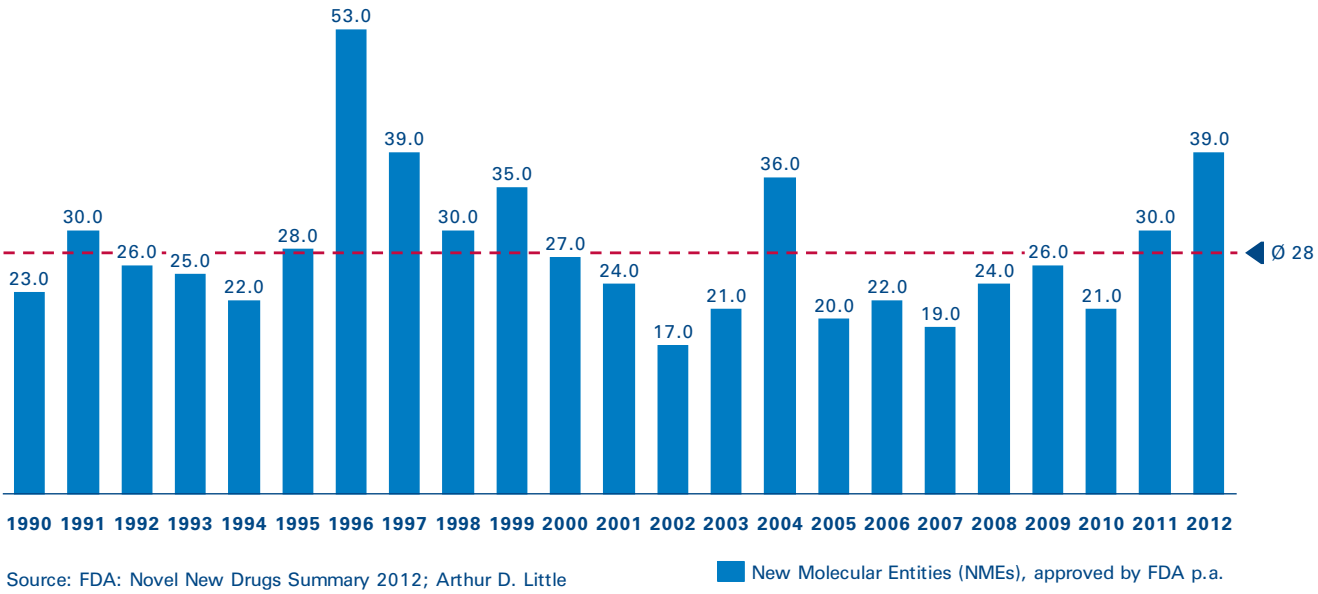
## Number of launches accelerating

Last year, the drug approval department of the US FDA recorded the highest number of NMEs launches since 1996 (Fig. 1). The number of launches was clearly above average and in addition, 41 new drug applications have been sent to the authority. This is good news after years of painful analysis on low productivity, ongoing restructuring in R&D, commercial / operational re-organizations and increasing pressure on medical evidence and prices.

## Big pharma needs to transform its launch approach

In the past, it seemed natural for big pharma companies to launch NMEs in known business areas and territories. Customer structures were well known and new products could easily be integrated into existing clinical programs. However, with changed market access requirements, new business models and technology platforms, changes need to occur. Companies need to transform their launch approach to meet these changes and ensure excellent results.

**Figure 1: Development of New Molecular Entities (NMEs), approved by FDA p.a., 1990 to 2012**




Source: FDA: Novel New Drugs Summary 2012; Arthur D. Little

## Biotech and midsized research companies are starting to commercialize

In addition to the well-known giants in the global pharma landscape, new players are starting to commercialize the products they have developed over the last few years. Biotech companies are beginning to commercialize and small and midsized enterprises (SMEs) that have previously focused on the R&D aspect of new technology platforms, are now striving to integrate into marketing & sales. On top of this, biotech companies' share prices are rising, indicating profitable business models. After years of building a core competence in research and development, these companies now need to execute commercialization.

## Pharmaceutical companies to meet new market access criteria

Governments and health insurance systems have reached a new state of maturity when it comes to evaluating and pricing new medical entities. Many countries have introduced new processes. For example, Germany has implemented its first general price negotiation process for new substances and indications. While the US has started its journey towards broader health insurance coverage, other important emerging markets such as China or Turkey, have introduced specific expenditure and price cutting measures for medicines.

While individual markets remain different, the common theme is to expect more evidence on value and to apply new pricing and reimbursement models. There is a strong trend towards more value for less money. In some countries, budget holders increasingly expect pharmaceutical companies to propose new reimbursement models such as pay for performance, capitation and risk sharing.

## Different levels of infrastructure require a customized approach

A criterion is not only set by authorities in each country or province, but also by the great differences in medical infrastructure, wealth and organization of healthcare in each market. While Western countries, some established Asian markets and few developing countries, such as Egypt and Cuba, have a dense infrastructure of healthcare delivery where drug therapies can be initiated, most markets in central Africa still lack this kind of infrastructure. Launching companies need to integrate these very different infrastructure levels into their value proposition and go-to-market approach.

## New delivery platforms emerge

Healthcare delivery is undergoing a transformation. What has been called the creative destruction of medicine[1] is actually the convergence of new developments in IT, telecommunications and medicine. Today it is possible for individual genes of a human being to be analyzed in a couple of days and micro-diagnostics can send permanent signals to a cloud server so that the vital parameters of a stroke patient can be observed. Communications through social media, collaborations with telecommunication companies and joint software development with IT companies will become an integral part of future sales processes in the pharmaceutical industry.

## Organization is key to handling increasing complexity

How do companies manage the complexity of a global product launch in a dynamic environment of emerging markets, new technologies and changing market access requirements?

Launch organization is key. It is essential to have the right people at the right spot and effective launch processes in place. Companies need to establish launch governance, a culture of transparency and information exchange and provide the appropriate structures and tools. The launch status needs to be tracked constantly to ensure that early signs of delays or underperformance are detected and tackled in time.

## Main reasons for failure

We have seen different reasons that cause the launch of an important NME to fail. These reasons stem mainly from three areas: the maturity of the company or business unit, familiarity to the market, and expertise of the involved staff members. Specific reasons for launch failure include:

- The drug candidate not being exposed to the right clinicians during the clinical phase; or if the drug candidate has caused mixed perceptions by key clinicians due to a lack of a proactive trial management and a lack of open discussions on the strengths and weaknesses of a drug.
- Regulatory, legal and license requirements not being assessed in detail resulting in temporary non-compliance. This hinders the company's ability to execute the launch-in-time.
- Market access strategies that are not produced early enough resulting in value dossier study gaps, a mismatch with local requirements, incorrect launch sequence or pricing strategy, and exclusions to reimbursement.

The results are weak sales ramp-up curves and stock-outs. Innovative products are frequently marketed by smaller companies without an established presence in the launch markets. In addition, there is a trend towards a more virtual

1 Eric Topol: "The Creative Destruction of Medicine: How the Digital Revolution Will Create Better Health Care", (2012)

**Figure 2: Pre-Launch phases and related key challenges**

| Pre-Launch phases | | | |
|---|---|---|---|
| **Development phase** | **Phase 2 studies/ proof of concept** | **Phase 3 approval studies** | **Approval and launch** |
| **Key activities** | ■ Set-the right strategy to best position the product<br>■ Integrate Market Access aspects into study strategy<br>■ Involve the right clinical centers and stakeholders into study program<br>■ Include country specific criteria into clinical trial program<br>■ Develop initial Launch Master Plan | ■ Initiate transfer of responsibilities and knowledge from R&D project management to commercialization teams<br>■ Shape medical messages and make available clinical results throughout the organization<br>■ Involve local teams<br>■ Prepare to meet distribution and license requirements<br>■ Engage in strategic Market Access discussions with stakeholders | ■ Consolidate launch activities<br>■ Initiate launch execution<br>■ Cascade launch master plan to countries<br>■ On-board launch specific resources<br>■ Finalize pricing<br>■ Test supply chains & distribution network<br>■ Intensify medical communication |
| ***Years prior launch*** | ***5*** | ***4 3 2*** | ***1 0*** |

Source: Arthur D. Little

operating model with centralized structures and distribution hubs. For such companies the launch complexity increases further, due to the number of different license requirements in certain territories.

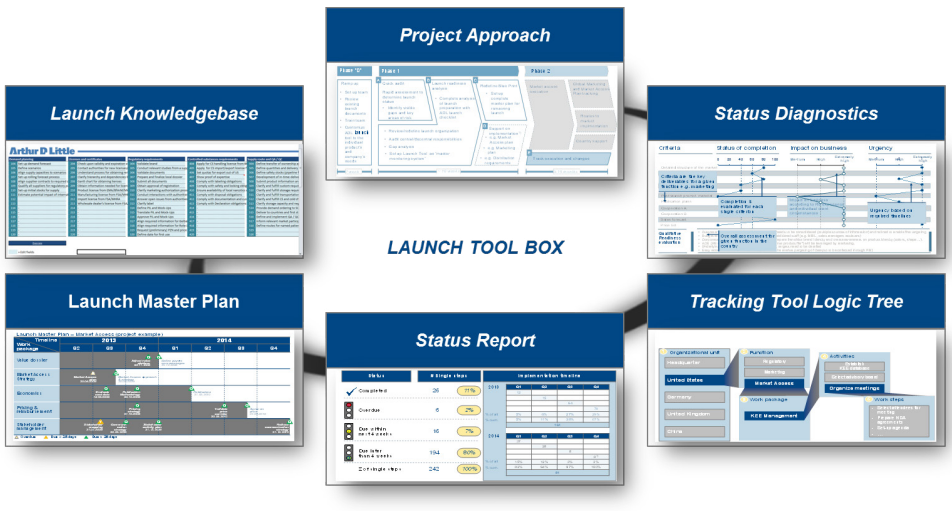
## Key success factors for launch

Performing excellence in market access processes is critical to gain maximum market access to the benefit of patients, providers, producers and payers. Stakeholders today expect suppliers to assume responsibility for care – a new therapy that creates value for society needs to be provided as soon as possible to the patients who will benefit.

According to our experience, it is not enough to analyze the market in terms of epidemiology, competitors, prescribers and previous ramp-up curves. This is a planning exercise that marketing needs to cover at an early stage of launch preparation but it does not ensure executional launch excellence.

Five years prior to the launch, it becomes critical to finalize the value proposition of the drug. The basis is clinical evidence and the expectations of market access stakeholders. In this phase, commercial and operational launch teams need to integrate into R&D teams in order to prepare for the successful market entry. Messages can be shaped, final pharmaco-economic studies can be designed to close evidence gaps and a launch plan must be developed and tracked to bring everybody up to speed.

**Figure 3: Pre-Launch phases and related key challenges**




- Arthur D. Little launch database with several thousand activities mapped
- Proven project approach to align client teams and achieve commitments
- Mature diagnostics to measure launch status and highlight critical gaps
- Launch planning tool enables team to track launch activities
- Master plan shows blueprint for launch

Source: Arthur D. Little

Companies need to intensively engage with stakeholders in key markets at this stage to ensure the new therapy will meet their requirements at launch.

Supply chain organization needs to translate commercial forecasts into demand plans and orders. Market access departments need to align their value and pricing strategy and prepare dossiers and campaigns. Stakeholder communication is key to avoiding misunderstandings and disappointments. The financial markets story needs to be told. (Fig. 2 overleaf)

## Our approach to launch excellence

The Arthur D. Little Healthcare team has extensive knowledge in the area of launch excellence. Based on the experience of numerous key launches collected in more than a decade of industry and consulting experience, we have carved out the critical path to success. This is how we created our comprehensive launch knowledge base. Our approach enables us to quickly assess launch readiness status in an initial audit phase. Subsequently we develop a comprehensive launch master plan, tailored to the specific drug, indication, company, geography and timeline until launch. Arthur D. Little implements these results side-by-side with the client management. Our launch tools allow cross fertilization between countries and teams. A traffic light system highlights areas of risk and delay. All launch critical activities can be tracked thoroughly to ensure maximum launch success. (Fig. 3 overleaf)

Based on our experience we know that after all it is the company's management who needs to make it happen. Alongside our project activities, we emphasize the idea of training and cross-learning. We provide a transfer of knowledge and tools to enable the company to fine tune and execute the launch master plan to the benefit of a successful launch.

## Contacts

**Central Europe**
Dr. Thilo Kaltenbach
kaltenbach.thilo@adlittle.com

**China**
Antoine Doyon
doyon.antoine@adlittle.com

**France**
Frédéric Thomas
thomas.frederic@adlittle.com

**Japan**
Maki Kurosawa
kurosawa.maki@adlittle.com

**Nordic**
Nils Bohlin
bohlin.nils@adlittle.com

**South Korea**
Kevin Lee
lee.kevin@adlittle.com

**UK**
Richard Eagar
eagar.richard@adlittle.com

**USA/ Latin America**
John Brennan
brennan.john@adlittle.com

## Authors

Sebastian Herzig , Dr. Thilo Kaltenbach

## Arthur D. Little

As the world's first consultancy, Arthur D. Little has been at the forefront of innovation for more than 125 years. We are acknowledged as a thought leader in linking strategy, technology and innovation. Our consultants consistently develop enduring next generation solutions to master our clients' business complexity and to deliver sustainable results suited to the economic reality of each of our clients.

Arthur D. Little has offices in the most important business cities around the world. We are proud to serve many of the Fortune 500 companies globally, in addition to other leading firms and public sector organizations.

For further information please visit **www.adl.com**



www.adl.com/Launch_excellence