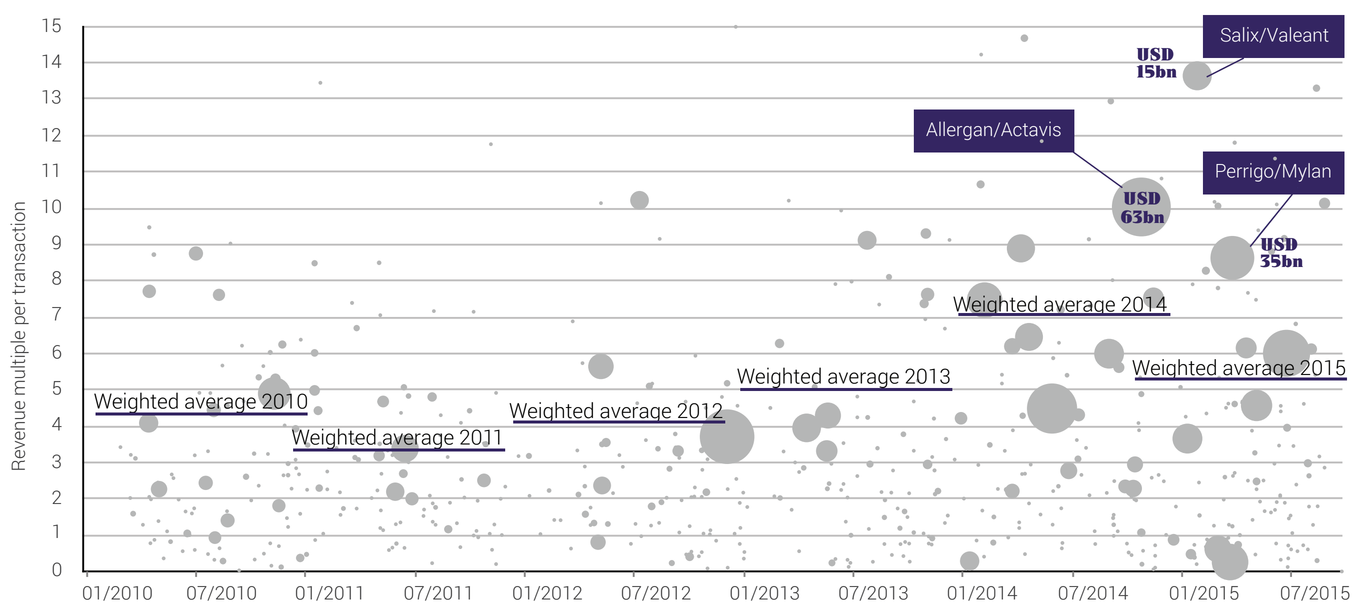
IMAP's view on how M&A is reshaping the **Pharma industry**

In 2015, Mergers & Acquisitions in the pharmaceutical industry was arguably at an all-time high. Up to the end of September, the total value of announced transactions reached US$ 850bn – not including the US$125bn merger which Pfizer and Allergan began discussing in October. Valuations reached eye-watering levels, with buyers often paying 6 or 10 times revenues for large, established companies with average growth rates. These valuation multiples are unseen in any other industry.

Feeding frenzy and collapsing champions

In part, the increased pace of deal making – some call it a "feeding frenzy" – and the high valuations are driven by quantitative easing and the availability of cheap money. Another fuel for M&A has been the desire of US-domiciled companies to use overseas cash piles and in some cases, change their domicile to a low tax jurisdiction at the same time ("tax inversion"). However, the strong undercurrent driving deal-making is the simple notion that "bigger is better".

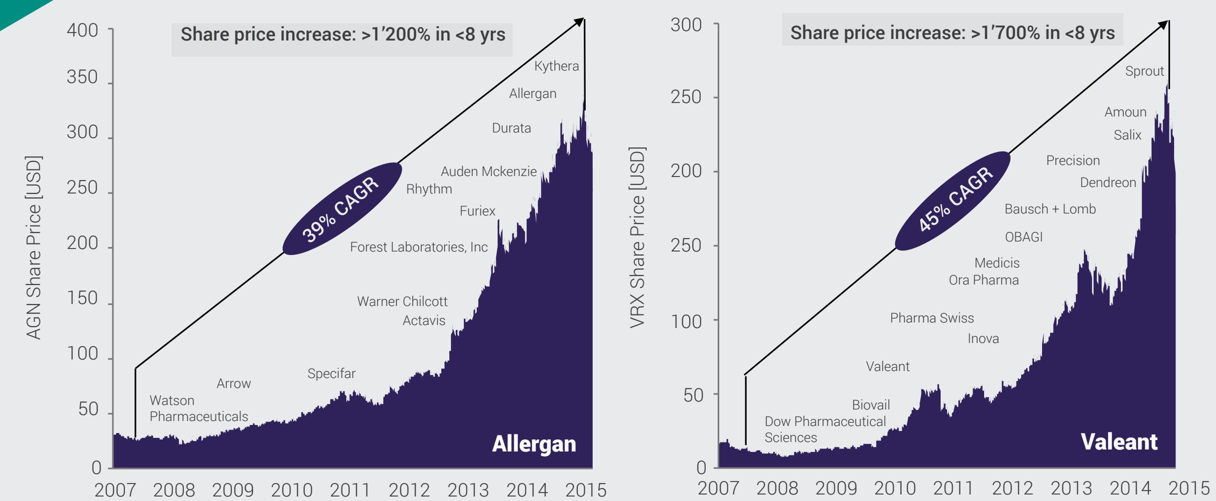


Transactions involving targets in the Pharma industry

Each bubble represents one transaction. Bubble size indicates transaction size, and the position on the y-axis the valuation relative to the revenues. Source: *MergerMarket, KP analysis.*

Some companies, most notably Valeant and Allergan, have implemented business models based largely on serial acquisitions and created phenomenal shareholder value.

In Valeant's case, value creation was just not sustainable, as can be seen by its stock market precipitation of more than 40% between the summer and late autumn of 2015. Investors started not only to doubt Valeant's ability to reduce its high level of debt (resulting from its many acquisitions) but also its business model in general.



Share price development of two serial acquires

Source: *Thomson Reuters, MergerMarket, Allergan/Valeant, KP research*

There is a growing feeling in the deal maker community that the overheated phase of M&A in the Pharma industry is likely to abate soon. However, there are strong strategic drivers for further M&A throughout the next decades, which we explain as follows.

Innovation meets inefficiency

Broadly speaking, the healthcare investors' mood is very positive. There are great technological advances and new treatments coming to the market which, for some diseases like Hepatitis Virus C (HCV) infection or certain types of cancer, deliver stunning results. Innovation is fueled by a healthy ecosystem of government-sponsored research, serial entrepreneurs, and savvy venture capitalists. All of which bodes well for both people's health and the Pharma industry in the long run.

On the other hand, the industry is still fundamentally inefficiently organized. Many players have not yet adapted to the new realities which have emerged over the last decade: firstly, evidence-based medicine as a basis for drug development and reimbursement and secondly, that funding for healthcare in general and drugs, in particular, is limited.

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"Better than the Beatles" problem

Many older drugs – often household brands – would fail the scrutiny of today's regulators because the clinical trials on which their claims are based do not meet the modern criteria of evidence-based medicine. Drugs can't be launched anymore based on a scientific concept or anecdotal evidence alone.

Today, regulators only grant marketing authorizations for a new drug if it can be shown that it is better (i.e. causes a stronger benefit and fewer side-effects) than the best treatment which is already on the market (the so-called "standard of care"). As medical development advances, beating this standard gets more and more difficult, hence the so-called "better than the Beatles" problem.

Rising standards and very cautious regulators have caused the average expenses for developing a new drug to amount to US$1.4bn (including the spending for programs which fail along the way). This excludes the cost of capital required which increases average total costs to US$2.6bn. Not surprisingly, financing of drug development is in the realm of fewer and fewer large companies.

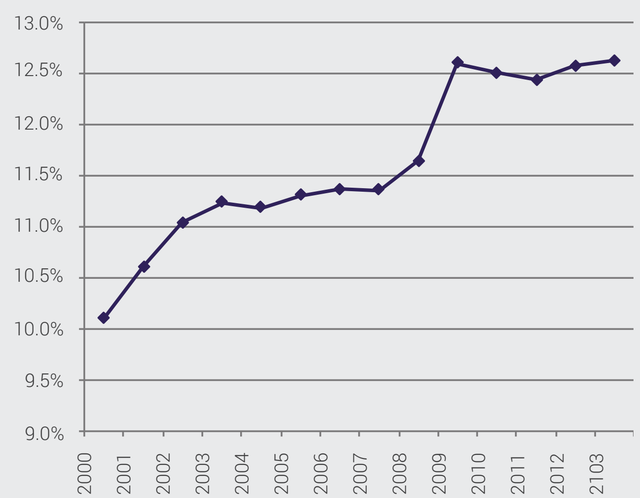
Rising costs but limited pricing – and bad public relations

While the cost of drug development increases, there are stronger societal pressures on drug prices. Cost-cutting efforts in the healthcare system (by payers or governments) find in Pharma companies easy and highly visible targets. The Pharma industry's average profitability is comparatively high compared to other sectors. Steep price increases as implemented in the US and highly public scandals raise eyebrows. The fact that most spending for drugs in industrialized countries is shouldered by society (through health insurances or benefits programs) makes pushing back on Pharma a rewarding political agenda point, as shown by Ms. Clinton's famous tweet sent in September 2015.

Healthcare costs rise consistently…

Total Health spending, % of GDP

OECD countries.

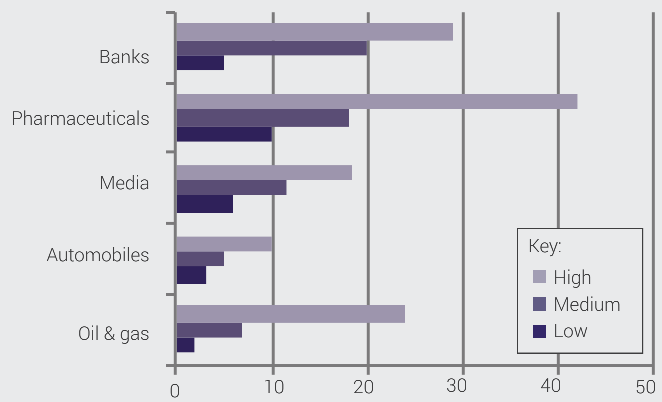


Source: *Worldbank*

… with Pharma one of the most visible drivers

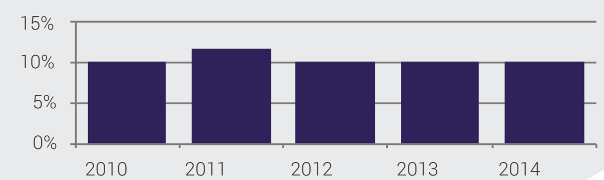
Pharma is one of the most profitable industries

Net profit margin of top 10 companies by sector, 2014 (%)



Constant price increases

Annual % increase, wholesale drug prices



Source: *Financial Times*

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Rationalizing benefits – health economics

To curb costs in healthcare and in particular for new drugs, payer systems in many countries (with the notable exception of the US) have started to apply sophisticated health economic computations to set the reimbursed prices for drugs. Payers set a price which reflects the monetary value of the improved outcome by the new drug versus the outcome of the standard of care along with the cost savings for the total health care systems the new drug will realize. For example, Gilead's Sovaldi (the "one-thousand-dollar-pill") which cures Hepatitis Virus C (HCV) infections will reduce the number of liver transplants and thereby leads to substantial cost savings for the healthcare system in the long term, even with the drug's high price tag.

Some Pharma companies go even further in order to show the value of their products and only charge for those patients for which the outcome is favorable. Such schemes are discussed more and more for oncological treatments but are also proposed by Novartis for its new heart insufficiency drug Entresto.

For less severe diseases which can be relatively effectively treated for most patients with drugs already on the market (such as blood pressure or heartburn), these health economy considerations may make the development of a new drug financially unattractive. If the best available treatment happens to be a generic drug with a low price, the improvement in effectiveness and safety must be vast to justify a price which pays back development costs.

4 strategic archetypes emerging

These two drivers - increasing costs of drug development and cost pressure on drug prices - will lead to a fundamental reorganization of the Pharma industry. IMAP's "4 strategic archetypes" model gives a conceptual framework for the industry structure as it evolves and is a good predictor for future, strategically driven transactions.

Absolute size

Medical excellence — **Originators**: Find, develop, launch innovative new treatments. Globally, based on strong R&D organization

Cost efficiency — **Providers of low-cost copies**: Manufacture and deliver standard quality at lowest possible costs

Generics | *Biosimilars*

Relative market share

Medical excellence — **Point-of-call specialists**: Provide comprehensive solutions for an indication / TA. Build niche competence

Consumer Marketing — **OTC**: Market consumer products with medical claim utilizing branding know-how

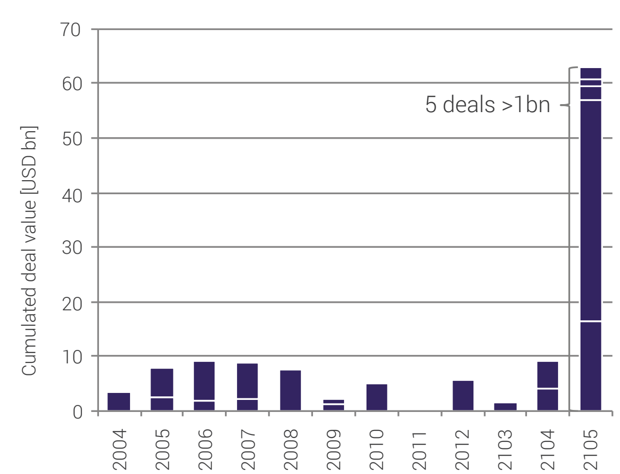
Source: *KP/IMAP*

Originators' mission is to find interesting therapies in the huge pool of innovative start-ups, develop them and bring them to market. Very few of the large Pharma players are big enough to finance a sustainable R&D pipeline, thus originators must combine big absolute size with medical excellence (and many other qualities, of course).

Providers of low-cost generic drugs must be big and have optimized capacity utilization at each level of the value chain, from the manufacturing of chemicals to their sales force (or, in many countries, their tender management). Consequently, generic drug manufacturers have consolidated substantially over the last years. The market of biosimilars (copy-cat products of biotech drugs) is just beginning to evolve and it is yet to be seen who the big players will be, though it is clear that generic drug providers will not compete in this market as they generally lack the skills in clinical development required to bring biosimilars to the market. However, it is already apparent that the winners will have the same features as generic drug providers today: huge size and razor-sharp cost control.

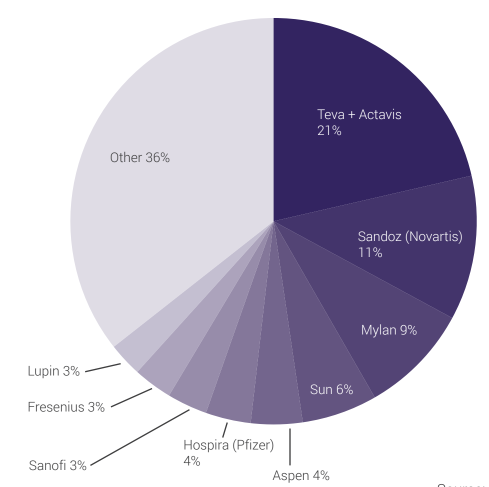
Acquisitions of generic drug manufacturers

Deal values >USD 1bn



Source: *MergerMarket, Evaluate Pharma, KP research*

Top 10 global generic drug manufacturers, 2014



Source: *Statista, 2015*

OTC drugs - medication which can be purchased by individuals without a doctor's prescription - follow a different dynamic. More closely resembling other consumer products like shampoos, they are driven by brands and consumer habits. This means that relatively small companies (by global standards) can compete with brands which are strong in a local market. In fact, looking at OTC products in Europe, we see that most brands are strong in only one market. Nonetheless, as the market matures, smaller companies will be acquired by global OTC companies such as J&J, Bayer, GSK/Novartis, or Perrigo and global brands will dominate the market in the long term.

Point-of-call specialists form another archetype that do not necessarily require huge absolute size. These companies provide products for one therapeutic area or medical condition. Their key objective is to combine medical excellence in their domain and a strong position in the relevant market. All orphan drug companies fall into this category, but also large firms like Novo Nordisk, who focus on diabetes drugs.

Obviously, there will be many exceptions to these four archetypes. For example, some types of drugs are very resistant to generic competition, such as topical drugs (treatments acting on the skin without entering the body), drugs which are applied with dedicated devices such as inhalators, or drugs which have only a very small market. Providers of these types of products may have less to fear from cost pressures than the others.

Manufacturing – Pharma's Achilles heel

While the 4 strategic archetypes will fundamentally change the industry landscape and with it the companies known to the patient/consumer, Pharma manufacturing is also undergoing significant changes. Historically, Pharma companies were fully integrated, incorporating R&D, manufacturing, and distribution. Comfortable gross margins and complex manufacturing processes have led to average capacity utilization in Pharma manufacturing of only 35%, whereas in related industries such as personal care, 85% capacity utilization is the target. The issue is exacerbated by the many successive acquisitions which result in unwieldy and inefficient manufacturing networks.

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Consequently, the last decade has seen the closure of many manufacturing units and the consolidation of production to larger sites. A next step in the evolution of Pharma manufacturing will see increased outsourcing to Contract Manufacturing Organizations (CMOs). This means not just the transfer of manufacturing to a CMO, but also the sale of integrated manufacturing units to a buyer who then also becomes a service provider.

We agree with McKinsey, the consultancy, that the Pharma industry's value change will morph to a system like that of the automotive industry: the brand owners (Pharma companies) will control the most critical elements of manufacturing whereas all other steps are outsourced to CMOs who will be organized in tiers; with some very large operators and a number of CMOs who are specialized and have strong positions in certain technologies.

More focus on strategic deal making

In conclusion, whereas much of M&A deal-making in the last few years has been driven by financial, tax or merely "bigger is better" considerations, future transactions will follow a pattern by which streamlining the businesses of Pharma companies. Many companies today do not follow a clear strategy or even mix different archetypes within one business. These players will have to focus their business on one strategic archetype which, given the size and complexity of their operations, will necessitate large-scale M&A. Some early examples are the proposed US$ 40.5bn sale of Allergan's generic drugs portfolio to Teva, and the famous strategy shift which Novartis engineered in 2014: selling its OTC, vaccine, animal health business and increasing its oncology portfolio, all in just one day.

In view of these developments, Boards of Pharma companies are advised to carefully scrutinize the strategic merits of transactions. Acquisitions to merely gain size (no matter what) may be detrimental. In turn, investors should steer clear from the "whales" who buy anything.

Dr. Christoph Bieri (left)
Chair IMAP Health Care Group
and Managing Partner
Kurmann Partners AG *(IMAP Switzerland)*
christoph.bieri@imap.com

Michel Le Bars (Right)
Managing Partner
Kurmann Partners AG *(IMAP Switzerland)*