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YEARS AHEAD



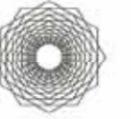
DEMAND PLANNING

IN THE LIFE SCIENCE INDUSTRY

AN EYEON WHITE PAPER

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1

EXECUTIVE SUMMARY

Great change is taking place within the life science industry. Driven by both external and internal factors, these changes are different from what was expected five years ago and are complicating business more than was previously imagined.

Although growth opportunities are still present, namely in emerging markets, niche products and biotechnology treatments, success demands that treatments are economically effective. Efforts to curb healthcare costs will put pressure on prices worldwide. Dealing with these price pressures and following the strategies to grasp growth opportunities will lead to a more complex supply chain. Strategies range from strengthening the pipeline through collaboration and mergers and acquisitions, to expanding the global footprint for a better local presence in emerging markets.

Assessing the consequences of these various dynamics is extremely challenging for planning professionals. Dealing with them represents an equally difficult task. However, an answer to the questions facing companies has already been found. Based on insights from the EyeOn Life Science Network and by working closely with leading life science companies, EyeOn has derived clear consequences and matching solutions, which are presented in this white paper.

Four key demand planning improvement drivers are identified:

- Higher performance: better forecasts translate directly into lower stocks.
- Flexible early stage forecasting: adapting the forecast to changing portfolios or health economics analyses, using scenarios.
- Differentiation: forecast more products in more different ways.
- Integration: the demand signal reaches the right levels as fast as possible.

These drivers give planning professionals the tools to define their own roadmap to be one step ahead of the rapidly changing life science industry environment.

2

INTRODUCTION



The life science industry has seen a long period of change in roughly the past decade. Right in between the 2012 and 2015 patent cliffs, the hopes are on new (biotechnology) products to offset the sales at risk from generic competition. Price pressure and decreasing R&D productivity have led to mergers and acquisitions as the initial response to maintain profitability and competitiveness, a popular response we still see today.

It will be no surprise that supply chain management becomes much more difficult as these developments unfold. In fact, we believe supply chain management will become a key success factor in maintaining healthy profit margins in the industry. The trends we see now all lead to increased uncertainty about the future demand for products. So within supply chain management, demand planning is already a vital business function.

This paper investigates how macro trends, industry trends and common industry strategies impact the demand planning function, and offers insights into how these can be effectively dealt with.

EyeOn recognizes the life science industry as consisting of 3 sectors: pharmaceutical manufacturing, biotech and medical devices. Most “big pharma” companies serve these three sectors. The distinction is nevertheless made to be able to address sector-specific trends and solutions.

This white paper is the first in an EyeOn series on planning and forecasting in the life science industry.

Life expectancy

Over the past 50 years, human life expectancy has risen by nearly 10 years in Europe and the United States. In addition, the birth rate has been decreasing in many Western countries and will continue to do so for the foreseeable future. As (more) people get older, the need for healthcare rises. The growth, however, will go hand in hand with the pressure to reduce costs.

Rising wealth in developing countries

As developing countries become wealthier, two important trends can be observed. First, the diets in these countries change to be more 'Western'. This brings with it the familiar non-communicable diseases such as stroke, heart disease and diabetes. For example, these diseases now account for 80% of deaths in China. Secondly, income growth in the middle class especially leads to demand for better healthcare.

In its July 2012 brief, the IMS Institute for Healthcare Informatics estimates that emerging markets will account for 30%, or 400 billion USD, of global healthcare spending by 2016. In 2011, the emerging markets accounted for 20%, or just below 250 billion USD. See "The Global Use of Medicines: Outlook through 2016" of the IMS Institute for Healthcare Informatics.

**Market growth**

Life science industry sales are expected to grow for the years to come. Overall prescription drugs sales are forecast to grow just below 4% per year until 2018. Yearly growth for medical devices is forecast at 4.5%.

Emerging markets

In terms of revenue increase opportunities, the entire life science industry is looking toward emerging markets. Whereas the Europe market is expected to grow at most 2%, or even decline slightly, the US will grow modestly with 1 to 4% annually, the emerging markets are expected to double between 2012 and 2016.

However, this growth comes at a higher price, or more specifically, a lower revenue. Where pre-operation margins in the US are 60%, emerging markets yield 35%. And the industry cannot dodge price pressure in these markets either. For instance, India is considering passing laws to cap medicine prices.

In addition, many emerging countries source their healthcare products in a different way: via tenders. Many companies are not very familiar with doing business via tender, as it has been only a small fraction of revenue.

Innovation

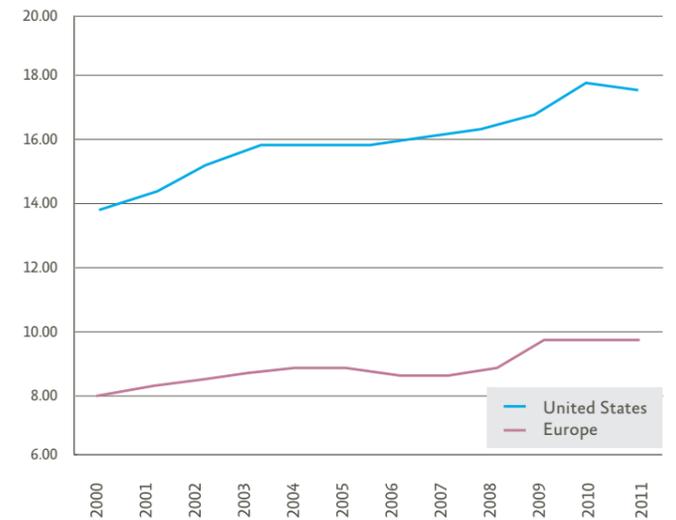
The key to sustained revenues and growth is innovation. But innovation is more than "just a new product". Product approval depends more than ever on the added value the product brings to the treatment area, in other words it is judged on its comparative effectiveness. This will hold for medical device and pharmaceutical companies alike.

Cost pressure

Rising healthcare costs induce sustained price pressure for life science companies especially in Europe and Asia. The same pressure is expected to arise in the traditionally high-margin market of the United States. This pressure comes from different areas.

First and foremost governments try to contain costs through regulation. A common measure in many countries is to issue directives that require doctors to prescribe generics, if available. Even India, considered an emerging market, has issued policies to cap drug prices and proposes regulation to require doctors not to prescribe branded drugs for more than a fixed percentage when generics are available.

Secondly, the healthcare providers themselves, in some markets pushed by insurers or authorities, are actively looking for ways to deliver cheaper healthcare.

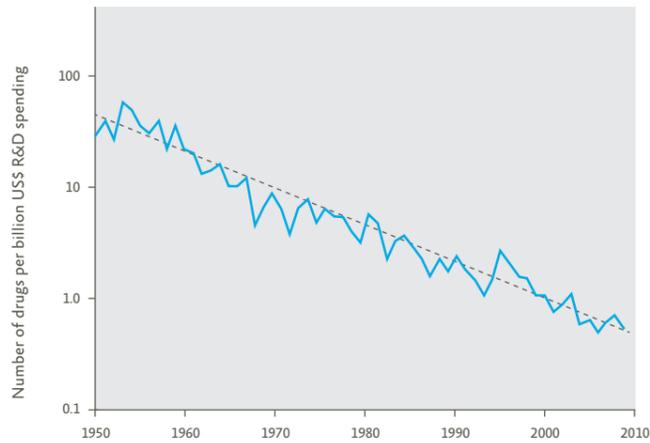


Health care expenses as % of GDP. Source: OECD.

4.1 PHARMA TRENDS**R&D productivity**

The number of new medicines approved by the FDA on a yearly basis is stable at around 20. In 2012, an exceptional number (39) of new molecules were approved. The development cost has never been so high: since the year 2000, less than one medicine has been developed per billion USD invested, whereas in the 1980's this figure was about eight medicines per billion USD. The key factor is how well the product adds value compared to existing treatments.

Approximately one third of the entities approved are treatments for orphan diseases with a smaller potential market, but where manufacturers can command a high price. The most growth is expected from the treatment areas Oncology, Multiple Sclerosis, Hepatitis C, Diabetes and Immunology.



Diagnosing the decline in pharmaceutical R&D efficiency, Jack W. Scannell, Alex Blanckley, Helen Boldon & Brian Warrington *Nature Reviews Drug Discovery* 11, 191-200 (March 2012).

Only with a strong pipeline can pharmaceutical companies sustain revenues. If in-house development does not provide enough promising treatments, the pipeline is built via mergers and acquisitions, or by collaboration. Especially small, promising biotech startups are often bought by large pharmaceutical companies to strengthen the biotech pipeline.

Patent cliff

The 2012 cliff is behind us and a second cliff, although smaller, is expected in 2015. The latest estimate is that \$230 bn of prescription drug sales are at risk in the next 5 years. At the same time, however, generic competition is expected to capture approximately 50%. Increasing revenues from orphan products and biological products are expected to offset the risk. In addition, some manufacturers opt to maintain volumes by reducing the price, such as Pfizer did when Lipitor went off patent.

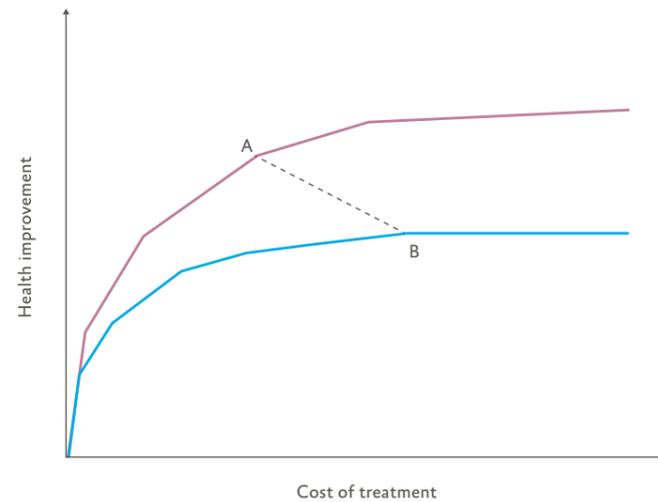
Generic manufacturers are thus preparing for increasing volumes, whereas pharmaceutical companies producing patented products need to, (1) produce at lower cost to be able to sustain a lower price, (2) support low-volume specialty markets and (3) increase manufacturing capabilities of biological products.

4.2 MEDICAL DEVICE TRENDS

Comparative effectiveness

Especially in the developed countries it has never been so important for manufacturers to prove the price effectiveness of their products as today. With many competitors providing similar products, the comparative effectiveness of a product compared

to a competitor's, or even a predecessor's is very important. Of course, budgetary pressures of healthcare providers will only speed up the trend.



Treatment A provides bigger health improvement at lower cost when compared to B. Source: *Comparative Effectiveness and Health Care Spending — Implications for Reform* Milton C. Weinstein, Ph.D., and Jonathan A. Skinner, Ph.D., 2010

New competitors

Competition might come from an unexpected corner. Some high-tech companies are expected to enter the market in the coming years. For instance, Samsung has already taken the first steps in this direction. These companies have the technical capabilities to produce high-tech products. In addition, their market has often forced them to be much more cost conscious than companies in other businesses.

Regulatory control

Regulatory bodies such as the FDA are treating medical device manufacturers ever more just like pharmaceutical companies. Both manufacturers and regulatory bodies will need to learn how to efficiently deal with stronger regulations. As with pharmaceutical companies, stronger regulatory control will impact processes, lead times and cost.

New care setting

The way healthcare is provided to patients is changing in many markets. Just as with the eyecare market, more care will shift to the first tier healthcare providers, or even commercial organizations. For instance, the initial consult for common health questions has shifted from the general practitioner to the pharmacy, or even the insurer in many European countries. A similar shift can be expected for the medical device industry.



The industry trends affect all life science companies to a certain extent. What common strategies can be seen? How are these trends turned into opportunities?

Emerging markets

The promise of emerging markets as an easy volume and revenue driver has been adjusted in past years. The common strategy has been to establish a local presence quickly and sell branded products or generics from existing portfolios. At best, this strategy has led to modest growth in these markets.

In the near future, this strategy will change in two ways. First, the emerging market isn't one market with a one-size-fits-all approach. To grow in a country the offering needs to be tailored to the current demographics (growth of the middle class), reimbursement policies and general healthcare structure. This has consequences for the product portfolio and pricing, to name a few. Secondly, local presence will increase to better understand the market and to more effectively deal with local regulatory and quality standards. This presence will therefore be across the board: in sales force, regulatory affairs, R&D and manufacturing.

5.1 PHARMA STRATEGIES

M&A and collaboration

As discussed, a large part of the most promising products and R&D investments are niche products to treat orphan diseases. A common strategy is to buy a pipeline via mergers or acquisitions. Collaboration has gained popularity as well, such as with Amgen and Actavis, AstraZeneca with Bristol-Meyers Squibb, and Pfizer (again) with Bristol-Meyers Squibb.

A second reason for mergers has been to diversify business. Innovative pharmaceutical companies buy manufacturers of generics to enter new markets or product lines. But there are examples of generic companies buying R&D driven companies as well.

Simultaneous with R&D and manufacturing occurring in a more complex setting, the sales model also changes to be closer to the customer: most often to be in direct contact with pharmacies or hospitals and in extreme cases even directly with the patient (e.g. in case of Genzyme).

Price pressure

The main drivers for lower prices in the future are patented products losing their patent and governments looking to cut back on healthcare costs.

As companies saw the patent cliff coming, defensive strategies were developed to keep market share or even fend off competitors. Affecting the bottom lines, most are price reductions to sacrifice margin for market share.

In general, all pharmaceutical companies are affected by price pressure from governments seeking to reduce healthcare costs. Increasing discounts reduces margins, but at least market share can be maintained. It becomes more complex to manage when treatments are sourced via tenders, which is a method that is becoming more popular also in established markets.

Outsourcing

In order to reduce costs and have fewer assets on the balance sheet, (parts of) supply chains have been outsourced to third party manufacturers. Although this trend seems to be continuing for now, especially for companies looking to free up capacity by outsourcing legacy products, the drug shortages and quality problems of the past years are often attributed to outsourcing gone too far. And the shortages persist, especially for injectable medicines.

It remains to be seen how this trend will evolve: will outsourcing continue, or will production be kept in-house, or perhaps insourced once again?

5.2 MEDICAL DEVICE STRATEGIES

Towards the customer

In the new care setting, as identified in the previous section, medical device manufacturers will succeed when they can migrate from simply making devices to offering full treatments and healthcare solutions. Of course, this provides an opportunity for further growth and expansion into new segments. On the other hand, services and products to support the sale of the core product need to be developed, sourced and supplied.

Healthcare economics drives business

Under pressure from comparative effectiveness, products are designed with the economics of healthcare in mind. The outcome of the comparative effectiveness assessment of a new product during its development lifecycle may influence the remainder of its lifecycle, the price setting and even the markets in which it will be introduced.

Likewise, if a competitor introduces a more effective product, the only option for a company is to reduce the price. "Effectiveness cliffs" will be a phenomenon medical device companies have to deal with in this new market.

Lastly, a strong focus on healthcare economics might also bring a new competitive edge: if a solution reduces other costs associated with the treatment (revalidation, medicine, or follow-up treatment) then this provides an opportunity to command a higher price and maintain margins.



6.1 R&D PLANNING & FORECASTING

As a new product comes closer to approval, the granularity of the forecast needs to increase to drive early business decisions: reserve capacity, buy / manufacture components or API, etc.

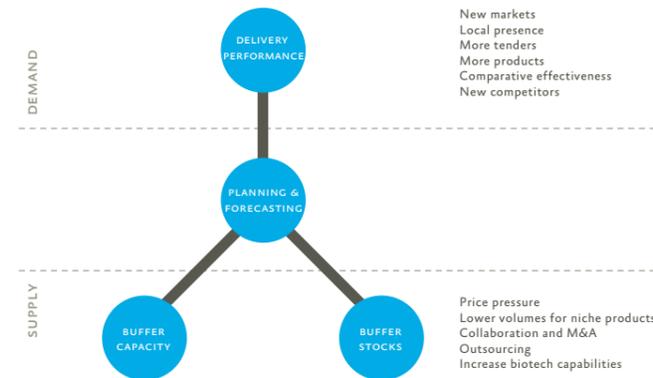
Good scenario management is necessary to effectively deal with the increasing regulatory control and pressure to prove healthcare economics, especially for medical device manufacturers. Typically, both aspects come into play in the later stage(s) of product development. The outcomes of regulatory assessments and healthcare economics studies can impact the time to market or price setting considerably. A concise scenario management process is needed to effectively translate these to form ramp-up volume decisions.

How do the trends and strategies identified in the previous sections affect the planning function, and more specifically demand planning?

A logical consequence of entering new markets, developing niche products and keeping the competitive edge is that the number of products increases. The number of channels through which the product is sold will increase as well.

Product price pressure and continued (or increasing) regulatory and quality control call for a more effective and efficient R&D project management and supply chain. Reducing the complexity of the supply chain is then a logical step. In reality, supply chain complexity will only increase for life science companies given the continued mergers and acquisitions (increased footprint!) and collaboration (shared supply chain!), outsourcing of activities, increasing local presence and added biotechnology facilities.

In short, the pressure on all three supply chain "trade off balloons" of delivery performance, capacity and stock, will increase. In those cases, planning and forecasting step in to optimize the supply chain and maintain delivery performance at the same time.



Increased importance of forecasting and planning.

The most straightforward consequence of the shifting trade-off between demand, capacity and stocks is that forecasting performance needs to improve. On the supply side capacity and inventories have to be utilized optimally to maintain or lower the cost of capital and contribute to the margin. On the demand side the delivery reliability to patients needs to be guaranteed.

A better forecast translates directly to lower inventories. In addition, forecast improvements lead to less bullwhip in the chain and will reduce re-planning and rescheduling in the factories.

We will now investigate how demand planning can contribute to this balance by tackling issues unique to the life science industry.

	Development	Production
	Forecast provided by Marketing	Forecast provided by Sales / Country Ops
	Forecast in €	Forecast in €
	Forecast in Q	Forecast in Q
	Range depends on unit prices	

Annotations in the table: A downward arrow from 'Forecast in €' to 'Forecast in Q' is labeled 'x unit price scenario'. A downward arrow from 'Forecast in €' to 'Target in €' is labeled 'x final unit price'.

Q and P forecast using scenarios.

Secondly, R&D forecasting has to deal effectively with large portfolio changes and complex development organizations. Promising products are added to the pipeline via mergers and acquisitions, and collaboration. In the case of acquisitions, knowledge of the treatment and its potential has to be built up quickly. Things become more complex with collaboration: processes need to be setup between two different companies to effectively share information. The basis for this is a clear R&D process with milestones, clear roles & responsibilities and strong governance. Especially in the phase when the market size and prices are determined, the scenarios have to be transparent and be clean of politics.

6 CONSEQUENCES FOR DEMAND PLANNING

6.2 MORE PRODUCTS TO FORECAST IN MORE DIFFERENT WAYS

Demand planning in the life science industry will have to forecast more products in more different ways. The big drivers are the growth in emerging markets, the new care setting for medical device manufactures and the focus on niche products to maintain margins.

	More products	Different ways
Emerging markets	Country specific products to meet country requirements	Higher share of tenders and spot sales
New care setting	Accompanying products within healthcare solution	Higher granularity forecast, point of sale forecast
Niche products	Customers require more service (e.g. large array of strengths) for the price	

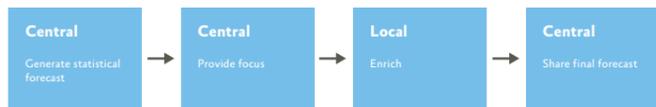
So how can this increase in complexity be handled? To answer that question we need to go back and define clearly the purpose of the demand plan.

The forecast is the leading input for making decisions on replenishments to customers, inventory and safety stock levels, available capacity and the production / purchase plan. Clearly, the horizon and the level of detail on which these decisions are taken varies. The latest forecasting technologies provide a good starting point for decision making.

1. Let Technology Help

Forecasts that are created statistically very often generate a forecast performance that can match the forecast provided manually by sales organizations. These organizations often don't have the time to minutely review the 24 month forecast of every SKU.

A statistical forecast is generated centrally for all SKUs and markets. Based on the forecast outcomes, focus can be provided to the local organizations. The forecast is then enriched by adding specific knowledge of the market.



Leveraging central and local expertise.

Some key points to consider when setting up a forecasting

process is the level of aggregation to be forecasted, how focus on the right products is ensured and how spot / tender market forecasts are dealt with.

2. Aggregate

For mid to long term decisions, not as much detail is required as for the short term. It is therefore key to aggregate the forecast where possible. An aggregated forecast has very important benefits that translate directly to a more efficient process:

- Better longer-term forecastability
- Better alignment with business processes
- Less effort and more focus for sales & marketing
- Less data to manage

The statement "we cannot forecast because it is a spot market" is often heard, especially in developing markets in Latin America and Asia. Aggregation actually gives much better insight into the demand, thereby enabling even a longer term forecast.

3. Focus

When products are forecasted in more different ways, getting the right focus is key to spending the available time in the best way possible. A good product categorization is the first step to provide focus.

	NPI	Mature items			EOL
		Stable demand	Medium volatile demand	Unpredictable demand	
Manual forecast	Runners	Review	Enrichment Focus	Enrichment Focus	Manual forecast
	Medium movers	No focus	Review	Review	
	Slow movers	No focus	No focus	No focus	

In the context of the life science industry, however, the basis of categorization should be differentiated based on the demand flow. Low volume, high margin niche products, for instance, will be slow movers by default, but they do warrant focus to be sure demand is met.

6 CONSEQUENCES FOR DEMAND PLANNING



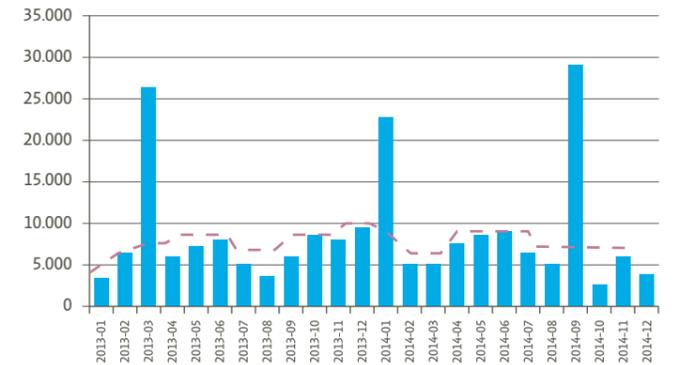
Demand type	Categorization
Regular demand	Provide categorization on the default ABC - XYZ level, per sales organization (country, region, ...). Leave out tender demand.
High granular demand for niche products	Focus on accounts with unstable demand. Review the accounts for which regular contracts are in place.
Tender and spot markets	Focus on the actual versus forecast at product level and change between cycles. Assess forecast on account level when one of the two changes is high.

Categorization tailored to the life science industry

6.3 TENDER MANAGEMENT

For tender demand, the default forecasting generation and enrichment process is insufficient. Tenders are "yes" or "no": either the full requirements need to be met in the short term, or nothing is delivered. It is therefore essential that the management process ensures explicit decisions about the risk of each bid.

The prerequisite for a good tender management process is the separate capturing of the tenders in the actuals and forecast. This way they can be excluded from the regular forecasting process and form a focused input to the tender demand management process.



Seasonality or tender demand?

A good tender management process, as compared with the normal statistical forecasting process, is defined specifically by the following five points:

1. Tender demand captured separately.
2. Financial assessment of potential bids.
3. An explicit decision to bid.
4. Explicit risk decisions to build stock and reserve capacity.
5. Tender / bid - based follow up of actuals versus forecast.

The time phased dynamics can be managed by having the detailed forecast together with the (aggregated) initial forecast in one view, such as in the example below. The risk decisions are made for the bids that will end in the short term. Mid to long term capacity and procurement decisions can be made using the development of overall requirements, as compared with the initial forecast (right part of the table).

Country	Product	Discussion												Each cycle check rolling and budget totals		
		Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Total year	Total rolling	Budget
UK	Product A	0	30.000	0	0	0	30.000	0	0	40.000	0	0	25.000	100.000	125.000	140.000
UNFPA	Product A	0	0	0	0	0	0	60.000	0	0	0	23.000	0	83.000	83.000	50.000
Myanmar	Product A	0	0	15.000	0	8.000	0	0	8.000	0	0	0	0	31.000	31.000	60.000
India	Product A	0	0	0	0	0	0	0	0	0	150.000	0	0	150.000	150.000	150.000
Egypt	Product A	2.000	0	0	0	1.000	0	1.000	0	1.000	0	1.000	0	5.000	6.000	7.500
	SUM	2.000	30.000	15.000	0	9.000	30.000	61.000	8.000	41.000	150.000	24.000	25.000	369.000	395.000	407.500

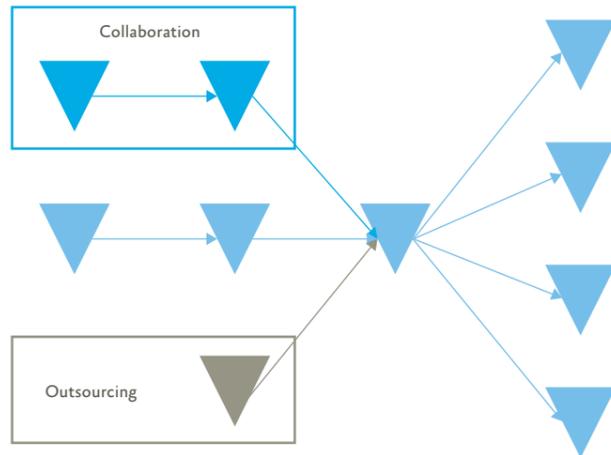
6 CONSEQUENCES FOR DEMAND PLANNING

6.4 DEMAND SIGNAL

On the whole, life science differs from other industries in that a large part of the supply chain is owned or fully controlled by companies. At the same time these supply chains are often geographically very dispersed and intertwined. The trends and strategies show that these supply chains are very likely to become more complex, with the main drivers being:

- Increased ownership of supply chain through mergers & acquisitions.
- Collaboration.
- Outsourcing.
- Increased local presence.

An example of such a signaling is net requirements planning or NRP. Within NRP, the customer forecast is translated directly to upstream levels (bulk production / API production) using the bill of material. Any stocks in the chain reduce the net requirements for the upstream level. NRP is fairly straightforward to calculate and it provides a look at the actual demand in the market, expressed in the unit of measurement familiar to the planner. It is a powerful tool to assess whether requirement fluctuations, as experienced by orders from downstream production, are structural or more bullwhip effects around very small variances.



Complex supply chains characterise the life science industry.

The challenge with outsourcing and collaboration is that these chains are not company-owned. The requirement to share information and decisions quickly needs to be addressed specifically for these parties: what is shared? When is it shared? The key here is transparency. Withholding information for any reason will lead to a lower service level, lack of responsiveness and higher stocks.

The demand planning function shares the demand signal correctly when:

1. Forecasts are gathered efficiently (e.g. via planning hub)
2. Forecasts are shared quickly and automatically
3. Quick aggregation is enabled for multiple purposes
4. Effects of demand changes on upstream levels are made visible

7 CONCLUSION



This paper is the first in a series of white papers on planning in the life science industry. It is an industry with unique challenges and developments. And these unique characteristics warrant extra attention to planning & forecasting.

Pursuing the opportunities of emerging markets, getting closer to the customer and product innovation inevitably leads to a larger portfolio of products sold in a wider array of markets.

On the supply side, operations need to work more efficiently under constant price pressure in an ever more complex manufacturing context.

The consequences of these trends and strategies for demand planning are captured in the four requirements:

- Early stage forecasting based on scenarios.
- More products that need to be forecasted in more different ways.
- More tender business requires a special tender management process.
- Demand signal needs to be more specific and more quickly integrated into the business.

This white paper provides insight into how these requirements can be met. The examples and related solutions fit into a solid forecasting process, e.g., fine tuning of categorization and installing extra in-process checks for tender forecasts. Observing these insights will be a first major step towards a road map for a best in class demand planning function.

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ABOUT EYEON

In striving for success, large companies have to continuously struggle against growing internal complexity. We help our clients manage this complexity by designing, implementing and executing excellent planning processes as a discriminating factor for this success. In order to achieve this, we develop and share knowledge about top level planning and forecasting, with constantly demonstrable return on investment for our clients.

ABOUT THE LIFE SCIENCE INDUSTRY PLANNING AND FORECASTING KNOWLEDGE NETWORK

EyeOn has set up a knowledge network for Supply Chain and Financial Planning professionals in the life science industry (pharma & biotech, medical devices and distributors). The network allows you to share experiences and best-practices concerning Planning and Forecasting with peer companies in the life science industry.

Joining the EyeOn Knowledge Network, Planning & Forecasting in the Life Science Industry, allows you to discuss the challenges that you are facing in your day-to-day business and exchange best practices with peers. Participation in the network is free-of charge.

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