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CHEManager EUROPE

THE NEWSPAPER FOR THE CHEMICAL AND LIFE SCIENCE MARKETS

Markets and Companies

Up close and personal with Lonza CEO Richard Ridinger.

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CPhI

It's that time of year! Catch up on the latest trends.

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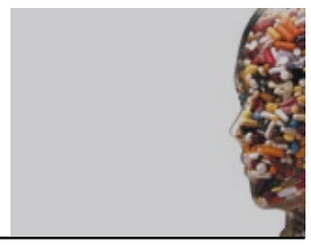

Newsflow

Markets and Companies:

Nobel Prize goes to three 'computer chemists.'

AkzoNobel invests €50 million in Western China.

Sanofi considers buying back L'Oreal's stake.

Rockwood finds a buyer for its TiO_2 business.

Ineos' Grangemouth dispute continues on.

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Pharma:

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Novartis considers shedding underperforming units.

GlaxoSmithKline India sees drop in bulk orders.

Carbogen Amcis beefs up ADC capabilities.

Merck & Co. wants to slash annual costs by $2.5 billion

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The Glass is Half Full

CPhI 2013 Exhibitors Demonstrate Positive Outlook

Optimistic — The worldwide economic situation has been a rocky one since the last CPhI in Madrid; many companies have had to revise their 2012 outlooks and are looking to invest more in less volatile areas of the industry. Ever-changing regulations worldwide have also been a challenge in the past year. But it's not all doom and gloom: In a time where there is no safe bet on new drug entities coming to market, custom manufacturers are seeing a boom in their business as pharma companies look to offset risk. Also, many companies have reported a shift of customers who tried their hand at working with Asian companies coming back to Europe. Brandi Schuster spoke to leaders from several different companies about what's moving their businesses. The interviews can be found in their entirety exclusively online by following the matrix barcode following each statement or by going to www.chemanager-online.com/en/tags/CPhI-2013.

Peter Seufer-Wasserthal, Senior Vice President, Pharmaceuticals, Codexis on the patent cliff:

"The patent cliff can actually be a very positive factor for a company developing new technology, e.g. a manufacturer of biocatalysts. It creates an opportunity for companies to reevaluate the process for making an API or intermediate. This allows a generic, but also the innovator company, to think outside the box and look at every available alternative to lower manufacturing costs. Codexis has on-going programs with many companies as a result of opportunities caused by the patent cliff."

Hall 3.1 Booth A53

Rudolf Hanko, CEO, Siegfried, on being a pioneer on the custom manufacturing frontier:

"Custom manufacturing started as kind of an extended workbench for the pharmaceutical industry. New APIs were being developed that required advanced chemical technologies compared to historic APIs and not all pharmaceutical companies had that know how. Also, the pharmaceutical industry was booming in a way that some were simply running out of capacity. But over the years, CMOs have evolved from being an extended workbench to an insurance system for the pharma industry."

Hall 3.1 Booth H25

Gabriel Haering, CEO, Cerbios, on the advantages of being a Swiss-based API manufacturer:

"Pharma companies who want to save on cost end up losing millions of dollars due to delayed clinical trials and, as a result, delayed product launches. A very simple example: if you consider a drug that can generate $350 million a year, every day of delay in the launch means a $1 million loss to the company. For a month, the lost turnover is $30 million! The final balance is in any case negative: $29.7 million lost considering that the company made a $0.3 million initial cost saving."

Hall 3.1 H20

Wolfgang Schmitz, CEO, Saltigo, on the increasing costs of AI development for agrichemicals:

"We work proactively with these trends by maintaining close relationships with all the major agrochemical innovators from the early stages of product development. We have noticed a tendency for CMOs to become more intensively involved in such projects than in the past. The time-to-market requirements have also become very ambitious. It has become quite essential to save time and to be the first on the market with a new product solution; this is where agrochemical companies look for recognized CMOs who can support them. All in all, I see a positive trend in agrochemical custom manufacturing for the coming years."

Hall 5, Booth F01

Laura Parks, President of DSM Pharmaceuticals, on growth in custom manufacturing:

"Yes, custom manufacturing continues to grow. Several large pharma companies have made it clear that outsourcing is a very important part of their strategy. On the other side, there will always be companies who decide that operational excellence and doing their own manufacturing is important. And, of course, there are companies who are slowly moving into working with CMOs. In effect, there are companies who have really worked hard to develop competencies in working strategically with CMOs while others are still working on what such a relationship could look like."

Hall 3, Booth A32

Matthew Dickman, international business director Pharma, Azelis, on potential in the Chinese pharma market:

"Selling APIs in China is not such a common or easy thing to do due to the amount of raw materials that are made in China. It's a different story with excipients. We have seen an increasing demand for value-added excipients in China, particularly to those companies who are formulating for the European or U.S. markets. This is going to become more common moving forward. There is a demand for the distribution of value-added excipients in China, and our intention is to provide a value-added service which mimics what we do in Europe."

Hall 3, Booth D45

Scott Thomson, senior VP, BASF Pharma Ingredients and Services, on the challenges in the pharma industry:

"The pharmaceutical industry is in a time of significant transition that creates both challenges and opportunities for our customers and BASF. Cost pressure and increasing market volatility caused by strong out- and insourcing of services are direct results from changing health care systems and the large number of medical products that come off patent. Additionally the industry is operating in an ever increasing regulatory environment that is varied across the globe."

Hall 3.1, Booth E19

Lars Hansen, VP, Novozymes, on the development of a European bio-based Economy:

"The development of the bio-based economy in Europe will contribute to re-industrialize and revitalize rural areas, thus providing tens of thousands of high-skilled research, development, and production jobs over the next decade, jobs that are solidly anchored in Europe's diverse regions; it is estimated that the global revenue potential of the entire biomass value-chain for biorefineries could exceed 200 billion euro by 2020. This is critical at a time where Europe is trying to get out of recession and is looking for sustainable growth opportunities. "

Hall 6.2, Booth E47

Michel Spagnol, CEO, Novasep, on the taking on a new role:

"The first year as a CEO is a unique moment: One brings an external view and confronts it with internal reality. This is the perfect time to bring new impulses and changes to the organization and teams. In my first month at Novasep, I discovered my colleagues' enthusiasm and dedication to the company and our customers' projects, which lead me to believe Novasep employees' mindset is a key competitive differentiator and a powerful driving force for development."

Hall 5, Booth C30

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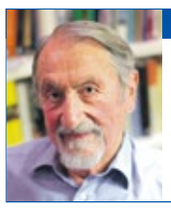
CONTENT

Nobel Prize for Chemistry Awarded to 3 'Computer Chemists'

AWARDS U.S.-Based Scientists Lauded for Multiscale Models For Complex Chemical Systems

In modern science, the computer has become just as important as the test tube, allowing scientists to create simulations so realistic that they are able to predict the outcome of experiments.



Martin Karplus
Harvard University
(Photo Stephanie Mitchell/Harvard Staff Photographer)

Michael Levitt
Stanford University
School of Medicine
(Photo Wiki Commons)

Arieh Warshel
University of Southern California
(Photo Wiki Commons)

Sweden — The Nobel Prize in Chemistry 2013 has been awarded to three scientists in the U.S.: Martin Karplus (Harvard University), Michael Levitt (Stanford University School of Medicine) and Arieh Warshel (University of Southern California). The Royal Swedish Academy of Sciences has honored the three for their work in the development of multiscale models for complex chemical systems. The scientists have paved the way for computer simulations that are now key in studying chemical reactions; they have devised methods that use both classical and quantum physics. For instance, in simulations of how a drug couples to its target protein in the body, the computer performs quantum theoretical calculations on those atoms in the target protein that interact with the drug. The rest of the large protein is simulated using less demanding classic physics.

Karplus, born in 1930 in Vienna, is a dual citizen of the U.S. and Austria. Levitt was born in 1947 in Pretoria in South Africa and is a dual citizen of the U.S. and the UK. Warshel is both a citizen of the U.S. and Israel; he was born in 1940 in the kibbuz Sde-Nahum in present-day Israel. (bhs) ■

Three Clariant BUs Sold, Renamed Archroma

Switzerland — Clariant announced the closing of the sale of its Textile Chemicals, Paper Specialties and Emulsions businesses to SK Capital. The three businesses are now operating under the name Archroma. According to a press release, the transaction will amount to approximately CHF 425 million, mainly consisting of a cash inflow of CHF 355 million and the transfer of pensions and other liabilities. Worldwide, 2,000 employees have transfered to Archroma. CEO is former DSM Pharmaceutical Products President Alexander Wessels. ■

Alexander Wessels
CEO, Archroma

Oman Oil Company Acquires Oxea

Oman — The Oman Oil Company (OOC), a commercial company wholly owned by Oman, will buy Oxo chemicals maker Oxea from private equity company Advent International for an undisclosed amount. With 1.3 million tons of Oxo chemicals and derivatives each year, Oxea generated sales of around €1.5 billion in 2012.

Oman is looking to strengthen its position in the global chemicals sector, particularly though its economic development program Vision 2020. The initiative is aimed at diversifying the economy across a variety of industrial and commercial activities in Oman and abroad while decreasing dependence on oil. ■

Solvay to Build Bicarbonate Plant in Thailand

Thailand — Solvay recently announced plans to build Southeast Asia's largest sodium bicarbonate plant in Thailand on its existing site in Map Ta Phut Industrial Estate (Rayong province, Thailand). With a total planned capacity of 100,000 t/a, this new facility will help meet the growing demand for high quality products from the region's dynamic healthcare and food markets, the company said in a statement.

Solvay will invest €20 million in the plant due for start-up in the first half of 2015 to supply its Bicar product range throughout the region. The project is fully supported by the Board of Investment in Thailand. ■

AkzoNobel Invests €50 Million in Western China

China — AkzoNobel will invest a total of more than €50 million in China to build new manufacturing facilities for its Powder Coatings and Decorative Paints businesses, the company said in a release. Both new facilities will be located in Chengdu with the powder facility scheduled to open in 2014 and the deco site starting production in 2015.

The announcement follows the recent start-up of commercial production of Bermocoll cellulose derivatives at the company's multi-site in Ningbo, which will serve the growing demand from customers throughout the region, as well as from AkzoNobel's own decorative paints business.

Ton Buechner
CEO, AkzoNobel

"China is playing an increasingly important role in our growth strategy," said AkzoNobel CEO Ton Buechner.

AkzoNobel currently employs more than 7,700 people in China, including 500 in research and development. ■

Teva Announces 5,000 Job Cuts

PHARMA Generics Maker Falls in Line with Other Companies

Teva Pharmaceutical Industries will cut about 5,000 jobs, 10% of its workforce, accelerating a cost-cutting plan as it prepares for lower-priced competition for its best-selling drug.

Israel — The world's largest maker of generic drugs by sales said it expects its overall cost-cutting program to save about $2 billion a year by the end of 2017. Teva is the latest in a string of big drug makers to take an ax to costs. Merck & Co has said it would cut annual operating costs by $2.5 billion and eliminate 8,500 jobs, or more than 10% of its global workforce. Others including Pfizer, AstraZeneca and Sanofi have also slashed staff numbers in recent years due to slowing sales growth, often due to competition from cheaper generic medicines — many of which are made by Teva.

When Teva announced the cost-cutting plan in December, it said savings of $1.5-$2 billion would take place over five years and it was unclear how many jobs would be lost. Now the company has said the

savings would be at the top of that range. It said $1 billion would come by the end of 2014 and 70% by the end of 2015. The majority of the savings will come from a reduction in the company's cost of goods, it said. ■

Petronas Awards Order to Hyundai

Malaysia — Hyundai Heavy Industries has won a $850 million order to build four liquefied natural gas (LNG) carriers from Malaysia's Petronas. The South Korean shipbuilder said in a statement the carriers are scheduled to be delivered from the second half of 2016. ■

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Searching for Targets in China

Acquisitions Gives Local Access to Foreign Chemical Companies

Deals are Worth the Trouble – With the ever-increasing importance of the Chinese market, foreign chemical companies obviously have a strong interest in buying local players. As a consequence, China leads chemical M&A activity in the BRIC countries (Brazil, Russia, India and China), accounting for two-thirds of deal volume in the first quarter of 2013, with six transactions worth more than $50 million.

Dr. Kai Pflug
CEO,
Management Consulting

This is despite the many obstacles for acquisitions in China. Good target companies are hard to find, and the majority of deals are initiated by proprietary networks and brokers. The success rate for closing deals is much lower than in Western markets.

Reasons to Go For Acquisitions

However, strategic investors — that is, companies already active in the chemical industry as opposed to equity investors — have a variety of good reasons to acquire chemical businesses in China. Buying a Chinese company may give a multinational corporation (MNC) access to local production facilities as well as to key local accounts. In addition, Chinese companies often have a low-cost distribution network, which is particularly important for mid-market products, where distribution has a higher share of the total costs. Such an acquisition may also allow execution of a two-brand strategy, such as done by DSM in its acquisition of ICD, a domestic producer of ultra-high molecular-weight polyethylene (UHMWPE). It helped DSM to fill some portfolio gaps and to add different price segments. By taking over existing facilities as well as customers, growth via acquisitions can be much faster than organic growth.

Overall, most of the recent acquisitions of Chinese chemical companies by MNCs were in the core area of the MNC. Acquirers tend to be global leading players in the respective areas, for example W.R. Grace, which in 2012 acquired the Chinese Noblestar Catalysts, expanding its production footprint in fluid cracking catalysts, or CABB obtaining local production capacity through the acquisition (via joint venture) of monochloroacetic acid producer Jinwei Huasheng. The overriding aim is to strengthen the local market position, add local production capacity and pursue lower-end markets. In contrast, chemical acquisitions by MNCs are rarely used to enter completely new markets, or markets with weak starting position. For example, before AkzoNobel bought Boxing Oleochemicals, it was already a leading player in specialty surfactants.

Defining Selection Criteria

Once the decision to search for an M&A target has been made, the selection criteria need to be defined based on the company strategy. This will result in a variety of criteria that may include, e.g.:

- Chemical subsegment (as mentioned above, likely to be one in which the acquirer is already active — few Chinese chemical companies are technologically attractive as stand-alone targets)
- Customer base (in particular regarding overlap/synergies with existing customers of the MNC — for example, AkzoNobel acquired Prime Automotive Coatings as this domestic company served a lower market segment than AkzoNobel itself)
- Annual sales of the target (too-large targets are not realistic while too-small targets may not be worth the effort, often resulting in a target sales range, e.g., $10 million to $100 million U.S.)
- Profitability (particularly relevant if acquiring company is margin driven)
- Regional focus (e.g., a foreign company may want to strengthen its business in the west of China)
- Ownership type (private companies are more likely to be successfully acquired than state-owned ones)
- Company image and culture (as this will influence the later ease of integration)

Target Lists

Once at least a few basic criteria have been determined, one of the most difficult tasks in the whole process is the preparation of high quality, long lists of targets. China's chemical markets are notoriously fragmented and fast-moving — the market participants change rapidly and it is not easy to get reliable data. The best approach is not to rely on a single database but utilize a variety of sources, e.g., databases from different providers, sourcing sites, market studies, expert interviews, etc. Hints from the own sales staff may highlight some particularly promising targets. On the other hand, the resulting long lists will contain a large number of companies that are either only traders of the relevant chemicals or may not even exist at all (not such a rare occurrence, either).

The subsequent elimination process should first focus on those criteria that are an absolute must and at the same time fairly easy to assess. For example, product groups or annual sales of a domestic chemical company tend to be easier to evaluate than the potential fit with the culture of a Western company. In the later stages (once only a handful of target candidates remain), more specific checks are vital, e.g.:

- Site visits
- In-depth analysis of products (e.g., quality, portfolio)
- Talks with customers
- Factual checks of company data

For example, for a specialty chemicals company we looked at about 2,100 companies in a specific chemical segment. Elimination of importers and traders brought the number down to about 700, which we reduced to about 50 based on more specific criteria (particularly minimum sales size). Only at this stage some of the criteria that are more difficult to assess (e.g., technology level, potential willingness to do a deal) were taken into account. The top 10 targets were then prioritized with the management of our client, leading to a detailed profiling of initially five companies.

Covering Targets in and out of China

On a side note, an interesting aspect of expanding the presence in the Chinese chemical industry was highlighted by the recent acquisition of PCTS, a specialist in biocides for paints and coatings, by Lanxess. Though the company is based in Singapore, 60% of its sales are generated in China. This example shows that a target search with the objective of expanding the China presence may also cover targets outside of China. In some industries for which the market has shifted massively toward Asia, even companies located in Europe may be worthy targets given their share of exports to China. Such deals may also help avoid dealing with some of the specific complexities of acquisitions in China. Acquiring Chinese assets of multinational companies is another option, an example being the recent acquisition of Bayer's vitamin premix activities in Chengdu by the Animal Nutrition and Health segment of DSM.

Word of Caution

Finally, a word of warning based on our project experience. It is unlikely such a search will result in finding the perfect acquisition target. Often at least one aspect of the target will be less than ideal. In particular, few Chinese chemical companies can be integrated without major investment in health, safety and environment (HSE) equipment. Only very few targets will be attractive from a technology standpoint — and if so, they are likely to be part of larger, less attractive operations. So a certain readiness for compromise is almost a precondition for an acquisition to eventually happen.

Dr. Kai Pflug, management consulting — Chemicals

Dr. Werner Heil, Heil Yang Group

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PORTFOLIO

Sanofi Interested in Buying Back L'Oreal's $12 Billion Stake

Repurchasing L'Oreal's 9% stake in Sanofi might make sense for the French drugmaker if the $12 billion holding is put up for sale, Sanofi's chief executive said. Chris Viehbacher told an investor conference the group had the resources to do "opportunistic" share buybacks, as well as making bolt-on acquisitions and potentially increasing its stake in U.S. biotech firm Regeneron Pharmaceuticals. Speculation over the fate of L'Oreal's stake in Sanofi has been fuelled by comments from L'Oreal's CEO, who said in August that the cosmetics company could buy back the $30 billion stake Nestle holds in it if L'Oreal in turn sold the €9 billion stake it owns in Sanofi. Asked about his potential interest in buying back L'Oreal's stake, Viehbacher said it was difficult to comment because the issue was highly conditional. Viehbacher said he did not exclude other share buybacks, but said these would depend on opportunities for acquisitions. Sanofi could also look at raising its stake in Regeneron to as much as 30%. Sanofi holds about 16% of Regeneron and said in February it has the right to increase this to a maximum 30% under its decade-long partnership with Regeneron. "The Regeneron relationship has become extremely productive for us," Viehbacher said. "Over time, it could well make sense to build our stake up to 30%. How fast we do that, whether or not we do that is a function of a number of different factors — but it is a bulky chunk of money to use." Regeneron's market value is about $27 billion.

Huntsman Buying Rockwood's Pigments Unit for $1.1 Billion

Huntsman is buying Rockwood Holdings's titanium dioxide pigments business for $1.1 billion cash, a deal that could mark the start of a long-expected shake-up in the volatile industry. The buyout, which is expected to close by June of next year, will make Huntsman second only to DuPont atop the market for titanium dioxide, a key white pigment used in paint, sunscreen and myriad other consumer goods. Huntsman plans to spin off roughly 20% of the combined pigments business in an initial public offering within two years of closing the deal. Huntsman would retain a majority stake in the new pigments business, Chief Executive Peter Huntsman said in an interview. The IPO would give investors the option to invest directly in either a TiO_2 producer or the legacy Huntsman Corp, which will have about $11 billion in annual sales after the offering and largely be a polyurethane foam producer. Huntsman's shares have "been disproportionately weighted to TiO_2," Peter Huntsman said. "This will be an opportunity for us to have investors that want to invest in pigments," he said. Pigments prices, which are closely tied to the economy, have started to rebound after five years of weak global demand and capacity increases that crimped pricing power. Producers have been trying to restructure their titanium dioxide businesses to shield themselves from swings in prices for the pigment used to whiten everything from sunscreen to toothpaste. Huntsman said the deal would give it 16% of global titanium dioxide capacity, up from 10%.

Total CEO Considers Increasing Its Asset Sales Target

Total may increase its target for asset sales to finance exploration and attain its oil and gas production goals, the Wall Street Journal quoted the French company's chief executive as saying. The oil major said earlier this year it planned to sell assets worth $15 billion to $20 billion by 2014. "Depending on how the plan goes and investors' appetite, I am considering amending the target," CEO Christophe de Margerie was quoted as saying, without elaborating, in a report published on the Wall Street Journal's website. He said he was maintaining his objective of increasing oil and gas production by an average of 3% a year between 2012 and 2015, the report said.

BASF Announces Cash Offer to Acquire Verenium

BASF said its American affiliate, BASF Corporation, has agreed to buy all the outstanding shares of common stock of biotech Verenium for $4 per share. The enterprise value is estimated at $62 million. The San Diego-based biotech generated sales of $57 million in 2012. In a statement, BASF said the price corresponds to a premium of 56% above the volume-weighted average share price for Verenium's shares in the six months prior to announcement of the transaction. The acquisition is expected to close in the fourth quarter of 2013. BASF said it will finance the transaction out of operating cash.

AkzoNobel: Phasing of Restructuring Charges between Q3 and Q4 2013

At the announcement of the Q2 results in July, AkzoNobel indicated that it had identified further efficiency and cost saving measures that would require €120 million of restructuring charges in the second half of 2013. In addition to the previously announced Performance Improvement Program costs this made a total of €256 million of restructuring charges that were expected to be incurred in the second half of 2013. It is now expected that the majority of these costs will be booked in the fourth quarter with over 20% to be booked in the third quarter. As previously indicated, the full year 2013 operating income is unlikely to exceed the €908 million of 2012.

Sabo Announces Agreement with BASF

Sabo said it has entered into an agreement with BASF for a license of the Chimassorb 2020 technology. Chimassorb 2020 combines exceptionally high UV and long-term thermal stability in applications such as polypropylene fibers and tapes. Demand for solutions based on Chimassorb 2020 has been steadily increasing, and the technology will grow as the product of choice for many applications. The acquisition of the license will further expand the product range of Sabo and complements the offer of high molecular weight monomeric light stabilizers already produced by Sabo in Bergamo, the company said in a statement.

Oxea Expands Alcohol Portfolio to Include 3-Methylbutanol

Chemical manufacturer Oxea said it is expanding its portfolio of higher alcohols with 3-methylbutanol (isoamyl alcohol), a versatile intermediate product for the chemical industry. Among others, it is an ingredient in the production of flavors and fragrances, cosmetics, fuel and lubricant additives and is used as a special solvent in the pharmaceutical industry, as well as in the paints and coatings industry. Oxea will manufacture 3 methylbutanol in Oberhausen, Germany. The product is already available in commercial quantities.

The Lifeblood of Business

Ashland on the Importance of Innovation

Transformer – It was one of the biggest headlines of 2011 — Ashland Closes ISP Acquisition For $3.2 Billion. When the Kentucky-based specialty chemicals company wrapped up the deal for International Specialty Products, it was also a turning point. Since the acquisition and integration of ISP, Ashland has been able to beef up its innovation and R&D capabilities. Brandi Schuster spoke to Jeff Wolff, Ashland's group VP of Pharmaceutical and Nutrition Specialties, about the transformation.

Jeff Wolff, group VP of Pharmaceutical and Nutrition Specialties, Ashland

CHEManager Europe: It's been two years since Ashland integrated ISP into the Ashland Aqualon Functional Ingredients commercial unit, creating Ashland Specialty Ingredients. Have the expectations been met so far?

J. Wolff: The 2011 acquisition of ISP truly transformed Ashland into a global specialty chemical company. With the addition of ISP's leading markets and personal care and pharma, we were able to double the size of Ashland Specialty Ingredients. We also tripled our research and development scientists and significantly have increased our number of patents. We actually increased our ability to penetrate the marketplace from an innovation perspective. Today, ASI represents around 35% of the $8 billion in annual sales for Ashland; it is absolutely a very important part of Ashland today, and it was a very good acquisition.

Tripling the number of R&D scientists must have really had an impact on the company's R&D clout. What can you tell us about new innovations coming out of Ashland?

J. Wolff: Innovation is really the lifeblood of our business, and our customers expect us to make products and technologies that will help them gain a competitive advantage in the marketplace. This is one of the reasons we have double our investment in R&D spending.

Specifically, we have made some significant investments in the emerging markets, such as in India and China. We have put labs in place to support growth in these areas, specifically around the technology part of our business. About 70% of our current R&D projects involve working with customers on a collaborative basis; this helps create value.

What regions are most interesting for Ashland in terms of pharma, both short and long term?

J. Wolff: There are attractive growth opportunities in almost all the regions of the world, both short and long term. We've obviously seen tremendous opportunity in Asia; we've seen continuous growth there recently, and we expect that to continue, particularly in line with the increasing prevalence of diseases and healthcare spending. Europe remains an important market for us, as does North America. Our new lab in Düsseldorf provides high-level technical support to Ashland's European pharmaceutical and nutraceutical customers. In addition to the lab in Germany, we also have pharmaceutical technology centers in Buenos Aires, Argentina; São Paulo, Brazil; Shanghai, China; Hyderabad, India; Istanbul, Turkey; and Mexico City, Mexico; and we will be opening a center of excellence in Wilmington, Delaware in the U.S. next summer.

If you look at places like China or India, it is difficult for companies to get a foot in the door sometimes. Do you have a specific strategy for those emerging markets in Asia?

J. Wolff: It's important for us to grow in these regions. We have also made people and lab investments. Ashland is clearly looking at the emerging regions and examining what the right approach is, be it people, lab investments or even acquisitions.

What are currently the main challenges facing Ashland in the pharma market and what does your company do to overcome them?

J. Wolff: One of the main challenges in the pharma market is the issue of solubility in APIs and how bioavailable it is inside the body. We are currently in the process of developing some new products in this area to address the needs of today's formulators. When an active is being developed, our customers need to make sure that it is also soluble in the body, and Ashland has unique technology in this area, which puts us in a good position to help.

Additionally, we operate global manufacturing plants under the GMP standards, and our customers depend on high-quality products.

Can you tell me a little bit more about what your strategy is for entering new markets? How much of a role do joint ventures play versus acquisitions?

J. Wolff: We are always looking for opportunities to grow our business. We closely examine both new and existing markets and look for chances to expand our base. When we have a new market of interest, we spend a lot of time to determine the best route of entry. This could include organic investments in personnel or assets to enable entry. It could also include an inorganic approach such as acquisitions, joint ventures, strategic alliances, etc. A host of factors come in to determining the preferred approach, and we try to be as flexible as possible to insure long-term success.

What about nutraceuticals? How important are those for your business?

J. Wolff: This is one of the growing areas of our pharma business. There are something like 1,800 nutraceutical companies out there right now, and while our focus is not necessarily to go after everyone, there are clearly targeted companies that are important for us. This is going to be a very large industry by 2018, to the tune of hundreds of billions of dollars, and we see an opportunity for us to participate in it from a global perspective.

▶ www.ashland.com

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Ineos Writes Down Value of Petchem

LOCATIONS Grangemouth Continues to Lose Money

Oil refiner Ineos has written down the value of its Grangemouth, UK petrochemical plant to zero, it said, further raising the stakes in a complex dispute with workers at the facility.

UK — The privately owned, Swiss-based refining and chemical plant owner Ineos said it had invested more than £1 billion since taking over at the Grangemouth plant in 2006, but that it continued to lose money.

"We had no option but to write down these assets," Calum MacLean, chairman of the Grangemouth Petrochemicals Business, said in a statement. "After four years of heavy losses, the petrochemicals business is effectively worthless. Without lower costs and an alternative source of additional raw material it will close 2017, at the latest."

Writing down the value of the plant could put pressure on the workers to accept lesser terms and conditions in their dispute with Ineos.

The Grangemouth petrochemical plant in Scotland is attached to a 210,000 barrel per day refinery, which Ineos jointly owns with PetroChina.

Oil traders are closely watching the dispute, as the refinery provides steam for a pipeline that brings crude oil from the Forties North Sea oilfield, one of the four crude grades that underpins the Brent benchmark.

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Corporate Overhaul at Lonza

New CEO Fine Tunes the Organization After Acquisition Phase

Strategic Maneuvers – When Richard Ridinger took over as CEO of Basel, Switzerland-based Lonza in May 2012, the 115-year old life science and chemical company with sales of just under 4 billion Swiss francs was ripe for a major overhaul. Not only had the latest economic crisis taken its toll on customers and countries. The appreciation of the Swiss franc against major currencies such as the euro and the dollar was threatening its financial resources, and a spate of recent acquisitions had weakened its focus.

Through the first decade of the new millennium, Lonza grew rapidly through acquisition, strengthening its life science position more than its specialty chemical activities. The takeover of U.S. biocides specialist Arch Chemicals in 2011 was a watershed as it added one-third to Lonza's size and shifted the focus back into a balance of the two very different segments. But while adding muscle and international presence, the company also gained unneeded bulk in some businesses not clearly aligned with its desired profile.

After settling into the chief executive's chair, the now 55-year-old German citizen who was executive vice president of the care chemicals segment and a member of the executive board at Cognis prior to its acquisition by BASF in 2011, quickly went to work analyzing Lonza's portfolio, its production structure and its approach to its markets to facilitate the needed reorganization. What he found was an unclear orientation, a complex operation with too many sites and a business philosophy driven perhaps too heavily by technology.

A Market-Driven Approach

Like many other players with a traditionally strong science base, Lonza's approach to the market was somewhat underdeveloped, Ridinger says. One thing was obvious: To survive in an intensely competitive environment, the venerable company that began life in 1897 at Gampel on the small river Lonza in the Swiss canton Valais not only would have to streamline its organization and consolidate assets, but change its approach from technology-driven to market-driven.

Along with strengthening the financial and organizatorial base, the goal of the efficiency scheme subsequently launched and slated to run until 2015 is to become more proactive in its approach to the markets. "Instead of developing a product and trying to find a market for it, in future we will first analyze the markets, decide which products we can supply or develop and offer the customer solutions," the CEO says.

Another of the foremost strategic objectives in the post-acquisition phase is to become more productive. Under its new leadership, the company's entire operational structure, including sites and support functions, is being examined. Another task will be to clearly define priorities. "If we want to get closer to the markets, we will have to decide which ones we want to be in," says Ridinger.

From his experience at Cognis, the manager understands that "it is possible to identify a target market and become a leader. This proactive approach is what I want to strengthen at Lonza. The company has an excellent basis from which we can improve our go-to-market skills. In some segments we are already doing this quite well. In others, we can do better."

Making Progress

After nearly a year of restructuring, tangible progress has been made. In Q1 2013, Lonza successfully priced a 300 million Swiss franc-denominated straight bond issue aimed at improving conditions. Core results for H1 2013 were better than expected, and the company is on track to realize cost savings of 100 million Swiss francs through efficiency improvements.

"Up to now, all the milestones have been met, and it is clear that we will get where we want to be," he says. To facilitate operational improvements, business teams are being directed to the target markets, and administrative functions have been grouped into regional business service centers.

In other crucial steps, the number of reporting segments has been pared to two — Pharma & Biotech and Specialty Ingredients. Industrial businesses are now under scrutiny to determine their compatibility with the new priorities. One non-core business has been shed, another carved out, a joint venture dissolved. A smaller European production site has been closed and restructuring of the company's biggest site is in progress.


Richard Ridinger became Lonza's CEO in May 2012.

At the end of 2012, the U.S. performance urethanes and organics subsidiary in Brandenburg, Kentucky, a legacy of the Arch acquisition, was sold to Monument Chemical. A carve-out process for the wood treatment activities has been initiated to facilitate a partnership or divestment. The latter was deemed not a core business for the future Lonza portfolio, Ridinger remarks.

The dissolution of the biosimilars joint venture with Israeli generic drugmaker Teva will allow the company to concentrate on its core expertise in contract manufacturing and cell line development without having to invest in areas not as strategic, such as clinical development and end-product commercialization.

This would have required more capital than initially envisaged, Ridinger says. Another factor was the intensifying efforts of ethical pharmaceutical manufacturers to develop their own generic versions of drugs coming off patent. This would have placed the company in competition with its customers.

As part of a plan to reduce the number of worldwide locations from the current 50, Lonza's Swords, Ireland, site, which manufactured biocides for anti-fouling paints and metal-working fluids — another Arch legacy — was shuttered in this year's second quarter and production moved to the U.S. and China.

The new corporate stratgey also foresees phasing out some of the company's activities in Hopkinton, Massachusetts in the U.S .and transferring some microbial biologics manufacturing operations to Visp, where this business will be concentrated in future.The VispChallenge efficiency program, sharpening the focus of Lonza's largest site (begun in 2011), is being continued.

Position in Life Sciences Pivotal

Most of the realignment so far has affected the chemicals side of the business. Retaining Lonza's leading position in life sciences, particularly Pharma & Biotech — which focuses on supplying active ingredients to pharmaceutical producers and custom manufacturing of drugs — will be a pivotal point going forward.

From its leading berth in what Ridinger has identified as the backbone of Lonza's business, the company can leverage its strong technology base to enter new markets in consumer markets and agricultural applications, sometimes with "only minor" adjustments needed. For both industries, we have the know-how to master a high technology level, whether it is recombining peptides, microbial fermentation, mammalian stem cells, or conjugation of biological and chemical molecules."

The Importance of Global Megatrends

For its future orientation, the medium-sized Swiss company —similar in size to Ridinger's former employer Cognis — has identified several global megatrends such as healthcare, hygiene, nutrition, water treatment and consumer products, where the CEO says "we can make a difference."

"This will not of necessity take into new directions," he stresses. While many companies now are striving to develop skills in fermentation and biotechnology, Lonza already has them and is physically present in the marketplace. In the specialty ingredients sector, "we are already number one in anti-microbials."

Alongside its strong position in fine chemicals and custom manufacture of pharmaceuticals, the company is also already an important player in water treatment. Currently the focus is on recreational water, such as swimming pools, but - mustering its expertise in anti-bacterial technologies - Lonza intends to move into public and industrial water treatment.

"We will deepen our footprint here within the next year," Ridinger says, "utilizing technology we already have in-house. Access to clean water will become crucially important to the emerging middle class in many countries." Personal care, where the new Lonza chief can contribute his expertise from Cognis, will also be a sharper focus.

The Challenge of the Swiss Franc

An obstacle more difficult to surmount, but still manageable nonetheless, Ridinger says, is operating from a country that has the world's hardest currency. But there are also advantages to being in Switzerland, he says. The economy is stable, the workforce highly qualified and loyal, the transportation infrastructure favorable and the relationship with local authorities amiable.

But "while this is a good place to be, all our sites need to be competitive," Ridinger says, explaining the need for efficiency improvement scheme at Visp, which initially raised concern among the company's unions.

When the ambitious company-wide realignment scheme is completed two years from now and the new strategy firmly in place, where will Lonza's growth come from? "We will continue moving up the value chain, and consider bolt-on acquisitions to add new technologies where needed," Ridinger says. One thing is certain, however. "We will not add more complexity."

Dede Williams, freelance journalist, in Basel

bit.ly/CMI_Lonza

UK Refinery Dispute Deepens as Ineos Snubs Conciliation Offer

UK — The Swiss-based oil refiner Ineos refused to go to independent arbitration in a dispute with workers at its Grangemouth refinery and petrochemical plant in Scotland, increasing the chances of a full-scale strike.

Ineos and Unite, Britain's largest trade union, have been engaged in a separate war of words about the future of the petrochemical plant.

Ineos recently announced a "survival plan" involving job cuts and changes to pension plans to keep the plant in operation.

On Oct. 7, across the complex began working to rule and refusing overtime in a dispute over Ineos's treatment of union organizer Stephen Deans.

The union said it could still escalate to a full strike, which would have serious implications for North Sea supply as steam from the plant helps to power the Forties pipeline.

Ineos on Tuesday morning turned down a union offer to take the dispute to the independent conciliation service ACAS.

"We're following due process with the investigation and that's not concluded and, until it is, we don't think there's anything to go to ACAS about," a spokesman for Ineos said.

Separately, Unite said it had agreed to discuss pensions, pay and conditions, and had submitted a transition plan, which Ineos would respond to by Thursday.

"I'm not optimistic, but our offer shows that accusations from the company that we are 'fiddling while Rome burns' are untrue," said Pat Rafferty, regional secretary of Unite.

An Ineos spokesman said Unite had not come up with new proposals but that talks with the union on the future of the plants were continuing.

Ineos says cutting costs is crucial to securing a loan guarantee from the British Treasury of 125 million pounds, and a grant of £9 million from the Scottish government.

It says it is investigating whether Deans' political activities with the Labor Party contravened company policies, and that it will announce its findings on Oct. 25.

The union says both the Labor Party and the police have found no evidence of wrongdoing.

The refinery that the chemical plant is attached to is owned jointly by Ineos and PetroChina. ■

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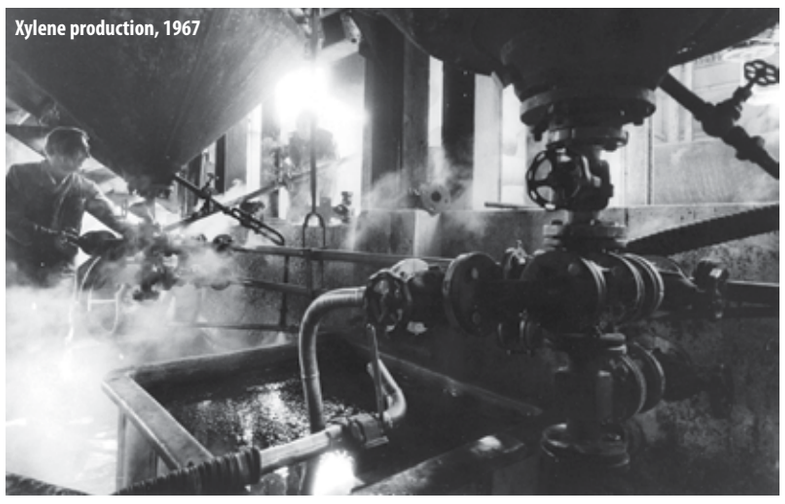
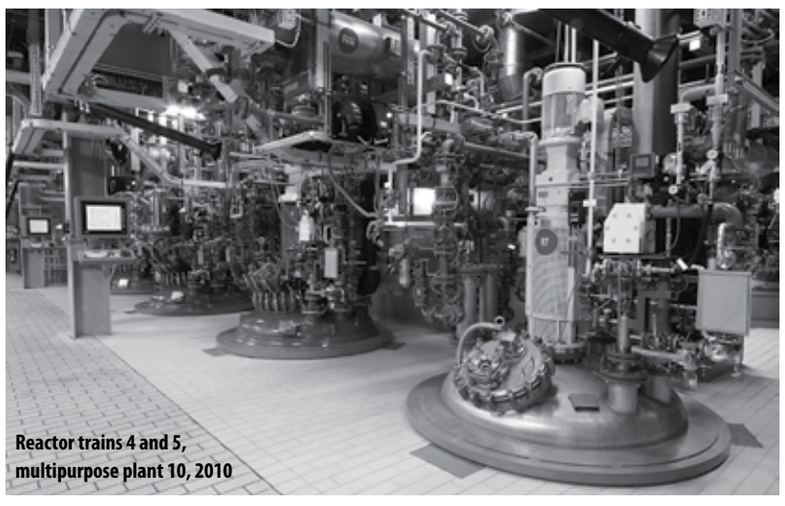
From Explosives to APIs

Dottikon Celebrates 100 Years of Transformation

Big Bang Beginning – In its 100-year existence, Swiss fine chemical company Dottikon Exclusive Synthesis (Dottikon) has transformed itself from a company specialized in explosives to a manufacturer of high-quality performance chemicals, intermediates and exclusive APIs. Despite this rather extreme change in direction, the company has always had one constant: Its dedication to its one-site manufacturing strategy. Brandi Schuster asked CEO and Chairman Dr. Markus Blocher about the company's unusual history and its unique position in the market.

Dr. Markus Blocher, CEO and Chairman, Dottikon


Xylene production, 1967


Reactor trains 4 and 5, multipurpose plant 10, 2010

CHEManager Europe: How did Dottikon go from producing explosives to APIs?

M. Blocher: In the beginning, Dottikon — at that time called Schweizerische Sprengstoffabrik (SSF) — was active in the mixing and production processing of the powdered explosive Aldorfit, used for tunnel construction. Due to the lack of raw materials during World War I, the forced back integration into distillation of gasworks tar waste was necessary to reclaim toluene, as well as its nitration to produce trinitrotoluene (TNT) – the majority of it for Swiss national defense.

After the drop of military explosives needs in the interwar years, the company found its way out of the crisis by entering into the production of gelatinized explosives made of nitroglycerine for civil purposes, and the purification of aromatic isomers for highly purified products through distillation and forward integration into the manufacturing of first chemical intermediates for the dye industry.

World War II also brought new explosives such as hexogen and nitropenta for military and later also for civil purposes. However, after the war ended in 1945, a fruitless attempt was made to compensate for decreasing business with the confederation and the Swiss army with civilian explosives and distillation products. It became clear that SSF could not survive with its existing product range. A change in direction towards higher, multi-stage intermediates for agrochemicals, dyes, pharmaceutical products and fragrances was gradually implemented over several years by extending the core technologies with catalytic hydrogenation and oxidation. Finally, there was a focused forward integration along the value chain to chemical end products, particularly APIs.

Dottikon is one-of-a-kind in the chemical industry, with its one-site strategy and being located in Switzerland, arguably one of the most expensive places in the world to produce chemicals.

M. Blocher: Yes, for commodities that's true. But if you sell value for money, cost-effectiveness is the right measure.

What is the philosophy behind the strategy?

M. Blocher: Our production site in Dottikon, located in the canton of Aargau, is specialized in hazardous reactions and employs highly skilled and qualified chemists. As performance leader, we are positioning ourselves as strategic development and manufacturing partner. Our safety culture created over the last 100 years guides innovative use of hazardous reactions, low-temperature and high-pressure chemistry, as well as continuous processing. This allows us to shorten conventional chemical synthesis routes, increase yields, selectivities and purities, and reduce waste. The versatile technology and equipment portfolio is used to design, develop and optimize chemical processes, and scale up from kilograms to multi-tons.

The combination of these factors at one site allows reduced decision and communication pathways, ensures rapid and efficient project development as well as clear and transparent communication with customers and results over all in superior cost-effectiveness and reliability.

At the beginning of April 2012 Dottikon founded an American cooperation, Dottikon ES America, Inc. Does this mean the era of being a one-site manufacturer is coming to an end?

M. Blocher: No. Dottikon ES America is a business development-only company and was founded to meet the growing demands of business development there. Any operational activities such as route finding, process development, scale-up, process optimization, large-scale production, validation, stability studies, recycling and waste treatment are performed in Dottikon, Switzerland, in line with our one site strategy.

How important is the American market for Dottikon?

M. Blocher: Although moderate, the U.S. economy is growing, and the fundamental outlook looks promising. In the context of competition for fiscal resources among different countries — and thereby the revival of trade barriers build-up — powerful nations as the U.S. are in a favorable position. Combined with the risk-taking "can do" attitude, a liberal job market and a long-term energy policy focusing on secure supply and economic prices, the U.S. is likely to maintain the unique competitive advantage in the long run that will foster innovation and re-industrialization. All these factors favor the demand for high-value and performance chemicals; therefore, America is an increasingly important market for Dottikon.

What other regions of the world are of importance to your business?

M. Blocher: Europe, with many countries having a leading position in the arena of industrial engineering and precision technology, plays an important role in supporting the U.S. innovation as well as the development of emerging markets. The high standard of living and the ageing population are further stimulating the demand for APIs, high-value and performance chemicals. These positive economic factors are, however, on the long-term thwarted by overwhelming bureaucracy, ever increasing fiscal quotes and misleading and idealism-driven over-regulation of labor and financial markets, as well as an energy and environmental protection policy that is mainly based on extra charges and their redistribution, hence missing effective environmental-friendly impact.

How big is the temptation to follow the trend to produce in low-cost countries?

M. Blocher: Nonexistent. We follow the principle of effective, not low-cost. It's not only the price; performance also counts. Our customers seek effective value creation: It's about effectively solving challenging chemical problems and delivering in full, on time, in spec and at agreed costs. Given the trend of regionalization, this becomes an even more important and strategic success factor.

Where is the future of manufacturing in Europe heading? Do you think it will pick up in the years to come?

M. Blocher: Success or failure of manufacturing in Europe is dependent on the willingness and ability of the political decision makers in each country to assure economically beneficial framework conditions. Education, labor, fiscal and environment policies have to be set liberally, farsightedly and sustainably. If these requirements are met, effective and reliable chemical manufacturing in European countries will have a market and therefore a future. In such an environment, there will be plenty of innovative customers willing to partner with a strategic development and manufacturing company having high performance aspirations and strong technological skills such as Dottikon.


Ammonium nitrate drying trough in the beginning of Schweizerische Sprengstoff-Fabrik AG (SSF) in Dottikon


Laboratory can be seen behind automobile. Aldorfit plant is next to horse and cart, naphthalene plant is in the background. Chimneys of the boiler house are to the left of the toluene plant.

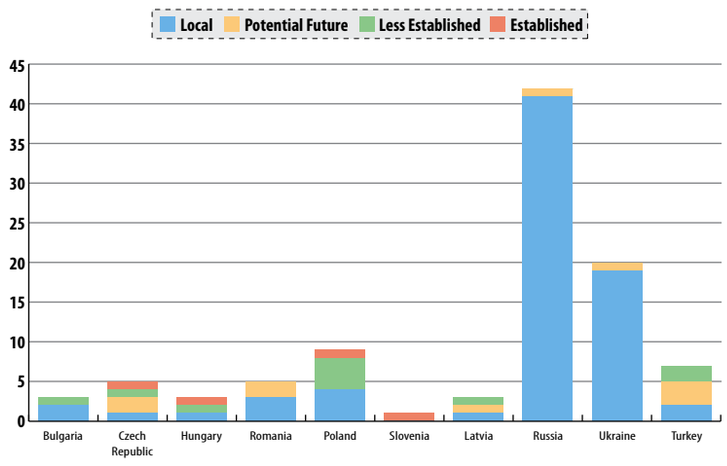
Visit Dottikon at the CPhI, Oct. 22-24, Frankfurt Hall 5 Booth C18

bit.ly/Dottikon

Russia's Booming Pharma Industry

Eastern Europe Shows Great Promise for API Manufacture

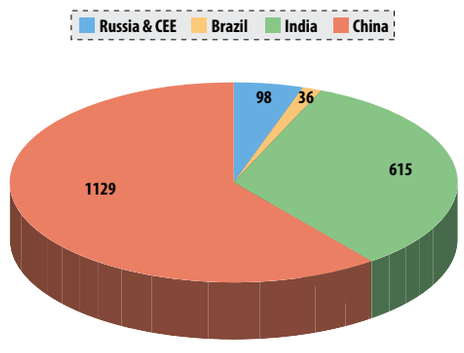
Number of API Manufacturers Based on Corporate Group Rating Fig. 1



Source: Thomson Reuters Newport Premium © CHEManager Europe

Thomson Reuters assesses the capabilities and experience of API manufacturers according to a proprietary scheme based on objective regulatory data. Companies range from those focused on supplying their local market to companies with years of experience supplying highly regulated markets.

Total Number of API Manufacturers in Russia & CEE Compared to Rest of BRIC Countries Fig. 2



Source: Thomson Reuters Newport Premium © CHEManager Europe

Potential For Success – There is great promise for innovative R&D, generics and active pharmaceutical ingredient (API) manufacture in Russia and the countries that make up Central and Eastern Europe (CEE). The development plan for Russia's Pharma 2020 outlines a pathway towards an increase in innovative drug development as well as domestic manufacturing output for internal and export use. Generic medicines will take up a majority of market volume and approximately 20% or greater of market value share. In response, there has been a cohort of companies seeking to start establishing platforms for production that will promote the initiative.

The Russian market is set to grow at twice the pace of the global pharmaceutical market, with growth estimates around 10-15% annually reaching an approximate market value of $43-60 billion by 2020 while the rest of the CEE forecasts exceptional growth as well. The Russian government intends to invest over $3.9 billion to incentivize companies to increase total domestic medicine sales and production to a level of 50% or greater within the Russian pharmaceutical market.

The most promising CEE markets, based on market size and potential revenue, include Poland, Romania, Hungary and the Czech Republic. With a number of developed companies like Zentiva (Sanofi), Gedeon Richter, Polpharma, Egis and other subsidiaries of larger multination corporations (MNCs), these countries have the most experience in producing pharmaceuticals for their regions. The CEE region also can serve as a contract manufacturing and research hub as well. Based on data from Thomson Reuters Cortellis Clinical Trials Intelligence, there are currently over 2,260 clinical trials in phases I-III within this region. The leading CRO locations are Poland with 682; Russia with 642; Czech Republic with 505; and finally Hungary with 431 ongoing trials.

Recent Investments into Infrastructure

With the promise of government funding and several tax incentives, there has been an increase in recent investments into the CEE and Russian regions. Cadila Pharmaceuticals has vouched to setup a new manufacturing plant in Russia's Astrakhan region at a cost of $150 million that will most likely be for API manufacture. Additionally, MSD (Merck) and Akrikhin just extended their line of local production to include five additional MSD drugs covering therapeutic areas including diabetes and asthma that will start in the beginning of 2014.

The news of Pharmstandard's recent acquisition of Singapore's Bever Pharmaceutical shows a shift in mentality that not every company will try to position API manufacturing at the local level. It is likely that Russia will continue to rely on companies in India and China to aid in the materials and imports needed to produce many of its drugs. Most of the substances needed for pharmaceutical production are still being imported at this time, but this may start to decrease as other major drug companies build capable plants in these regions. Figure 1 shows some of the other notable deals, which are comprised mostly of manufacturing investments and joint ventures into these regions. Joint ventures into Russia and CEE are necessary in order to create a relationship with local parties, in order to utilize expertise in their respective territories and also circumvent language constraints (fig. 1).

Points To Address

With any of the emerging markets, there are barriers to entry. Russia's regulations differ from the rest of the CEE region, and many of these countries have been trying to improve regulation and authorization procedures. In part with the groundwork laid out by the New Collaboration Agreement between Drug Regulatory Authorities in Central and Eastern European Countries or (nCADREAC). In order for pharmaceutical companies to continue their investment, however, the Russian regulatory authority must continue to improve upon the Law on the Circulation of Medicines passed in 2010. It currently stands that if a drug maker wants to register a generic medicine in Russia, that bioequivalence studies must be repeated in Russia and also that the reference drug should be purchased at the local level. This could inflate the cost of registering products drastically.

Historically, there have been intellectual property and transparency issues as well, which hopefully will be alleviated with Russia's ascension into the World Trade Organization (WTO) and the creation of a specialized IP court earlier this year in February. There are some additional barriers that will ensnare companies looking to produce such as protectionist penalties, which directly go against standards of the WTO. The ban that is being addressed would block participation of foreign pharmaceutical companies with respect to the tenders for the public procurement of medicines. This is only the case when there is a presence of at least two similar therapeutic drugs produced by local manufacturers already available to the market. Although protectionist efforts may deter interested companies, Russia and certain CEE countries will also need to consolidate and revise internal reimbursement schemes to allow pharmaceutical companies to time the release and pricing of drugs appropriately.

Along with the issues mentioned above comes the fact that there are still less than 50 Russian-owned companies with the capability to produce API and only a fraction of finished-dose companies when compared to India and China (figs. 2-3).

Looking Ahead

Russia and CEE might seem overshadowed by the number of API manufacturers in India and China, but it also contains room for companies to set up infrastructure in the coming years and establish themselves, especially for clinical trials. Clinical trials and R&D spending have traditionally been an inherent necessity for drug development by the pharmaceutical industry, but these future costs will need to be contained and countries within the CEE offer a skilled workforce with a less costly location to do so, in comparison to Western Europe and the U.S. Patients are often more willing to participate in clinical trials for access to newer medicines and thus the recruitment process is overall quicker than in western countries. As the population ages and the middle class expands, the most influential therapeutic segments will typically be oncology and cardiovascular medicines for these regions.

If the Russian government continues to provide funding and can improve upon regulations that will invite foreign investors to support domestic production of pharmaceuticals, Russia could become a renowned hub for the industry.

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Company	Investment / Target	Value (U.S. $)	Details
Teva	Manufacturing Plant in Yaroslavl, Russia	$50 million	Oral Dosage forms; expected commercial production Q2 2015
Aurobindo	JV with OJSC DIOD	Undisclosed	OTC products in Russia and also sourcing penicillins, cephalosporins to Kazakhstan and Belarus
NovaMedica	JV with RUSNANO to build manufacturing plant	$85 million	Also inted to invest upwards of $760 million in emerging life sciences companies
Takeda	Manufacturing Plant in Yaroslavl, Russia	$95 million	Fully operational in 2014, plans to produce Cardiomagnyl and Actovegin
AstraZeneca	Kaluga Region Plant	$187 million	Planned production near end of 2014
Abbott Laboratories	Petrovax & PharmaStandard	Approx. $300 million	Developing influenza vaccine
Bayer	JV with Medsintez	Undisclosed	Moxifloxacin, ciprofloxacin, and nimodipine
Novo Nordisk	Insulin Plant in Kaluga Region	$100 million	Expected start of manufacture 2014
Sanofi-Aventis	ChemRar innovative drug partnerships	Undisclosed	18 month agreement
Recordati	Acquisition of Poland Farma-Projekt	$22.5 million	Produce cardiovascular and urological medicines as well as dietary supplements
Zentiva	Into current plant in Bucharest	$12 million	Due to an increase in exports to Germany and the UK this year
Teva	Plant in Gödöllő, Hungary	$110 million	Sterile injectable plant mainly for cytotoxic drugs

Here Comes The Bribe

Endemic Corruption Holds Back Emerging Markets

Barrier To Business – One of the defining trends of the past three decades has been globalization. In order to take advantage of low-cost labor in emerging economies, companies have unbundled production processes and outsourced manufacturing to remote markets. As economies, such as China, move from "emerging" to "emerged" status, manufacturers seek new, even more remote markets to take advantage of lower rates of pay. Such countries may be unstable, have a fragile security situation, and weak legislative and judicial systems, factors that have allowed corruption to become endemic in society and government.

One of the little-understood implications of this trend has been the exposure to corrupt practices that companies face when establishing operations in emerging markets. This not only applies to manufacturers but also to the logistics companies they employ.

John Manners-Bell
CEO,
Transport Intelligence

Obstacle To Development

Although corruption is not a subject many companies are happy to discuss, there is no doubting its importance. Corruption has been identified as the leading barrier to conducting business in 22 out of 144 economies, according to the World Economic Forum's Global Competitiveness Report. In fact the WEF describes corruption — the widespread and deep-rooted abuse of entrusted power for private gain — as the single greatest obstacle to economic and social development around the world. This includes fraud, bribery and kickbacks but can also include in other contexts non-financial forms of corruption, such as preferential treatment in the assistance or hiring processes for family members or friends, or even the intimidation of staff to turn a blind eye to illegal acts.

Part of the problem is cultural. In many parts of the world kinships and affinity to social networks are more important than in the West; therefore, it seems perfectly legitimate to provide job opportunities or kickbacks to friends and family. Even in the EU this can be a problem, especially on the eastern border. For instance, the Russian ethnic community on both sides of the Russian/Latvian border has been identified as being complicit in organized smuggling networks, and the border officials are drawn from the local community. Bribery is often not needed to ensure that a customs officer turns a blind eye, as a culture of exchange of favors already exists.

According to a survey by Transparency International, a consultancy involved in highlighting corruption on a global basis, emerging markets score particularly badly in terms of perceived levels of public sector corruption.

Countries highlighted by the organization for high levels of corruption include Somalia, North Korea, Afghanistan, Myanmar and Sudan — the bottom five in the ranking of 174 countries. This is perhaps not surprising given that these countries could all be classified as failed or on the verge of failing. Central Asian countries such as Tajikistan, Uzbekistan and Turkmenistan all perform poorly as well.

However, it is perhaps more interesting to look at the performance of the major emerging countries — for example, those included in the BRIC group. On a list of 174 countries, Brazil had the "cleanest" public sector of the four appearing in 69th position, followed by China in 80th. India was 94th and Russia lagged behind in 133rd position.

Given the importance of these countries to the logistics sector, it is not surprising that international freight forwarders have run into trouble when attempting to do business in them. Nigeria, a country with massive potential for economic growth, appears at 139th in the list.

High Standards, Low Corruption

At the other end of the spectrum, some countries in emerging regions have exceptional records in addressing corruption. The two most outstanding are Singapore (fifth) and Hong Kong (14th), both of which have high regulatory standards and governance. In the Middle East, the United Arab Emirates performs best (27th). It is no coincidence that these three countries have very successfully transformed themselves into global logistics hubs, with efficient administration and customs processes largely untroubled by corruption.

One of the reasons the logistics industry — and freight forwarding in particular — is so vulnerable to corruption is its close engagement with customs officials. In the developing world, government employees are often poorly paid, and there is an understanding that they will make their wages up from "facilitation" payments made by forwarding and express companies to ensure fast clearance of goods. In many countries, particularly in Africa (but certainly not restricted to the continent), corruption is so deeply ingrained in the system that it is seen as an operational cost to be absorbed within the cost of moving goods.

In any case, customs corruption is a two-way problem. Not only do customs offices attempt to solicit bribes, but they are also the targets of bribes from organized crime, attempting to smuggle goods across borders, and in some cases private-sector companies; the involvement of the latter organizations is by far the most frequent as companies attempt to expedite slow bureaucratic processes.

An investigation by Indian authorities found that the number of people involved in bribery schemes goes far beyond just logistics companies and customs offices. In one instance it was estimated that 100 people at Nhava Sheva port, Mumbai, were involved, including middlemen and couriers collecting bribes and delivering them to the officers. Couriers may even take money directly to officers' hometowns or villages and give it directly to their families.

In Africa, customs corruption affects local traders and international shippers alike. Cross-border activity in parts of West Africa is characterized by the endemic payment of bribes and harassment. A common catch phrase of customs officials is, "Sans argent, on ne passe pas."

One of the problems highlighted about trade with Nigeria has been the length of the restricted goods list, which prohibits or limits the importation of goods from neighboring countries. This means that smuggling of these goods is rife, and so is the payment of customs officers by organized crime.

Time And Money

Another problem is the extent of bureaucracy and delays. An African Development Bank report found that the average customs transaction involves 30-40 different parties, 40 documents, 200 individual pieces of data (30 of which are repeated at least 30 times) and the rekeying of 60%-70% of data at least once. This is not only an issue on the importing side of the border — there are controls to go through on the exporting side, too, doubling the bureaucracy. Waiting time for a truck at a border crossing can be anything up to three days. Customs clearance adds an estimated $185 for each day delayed to the cost of a consignment. It is for this reason that many shippers prefer to bribe customs officials to cut the process short. Of course there has to be a willingness on both sides of this transaction.

This article has been excerpted from John Manners-Bell's forthcoming book, "Global Supply Chain Risk: Understanding Emerging Threats to Global Supply Chains," published by Kogan Page.

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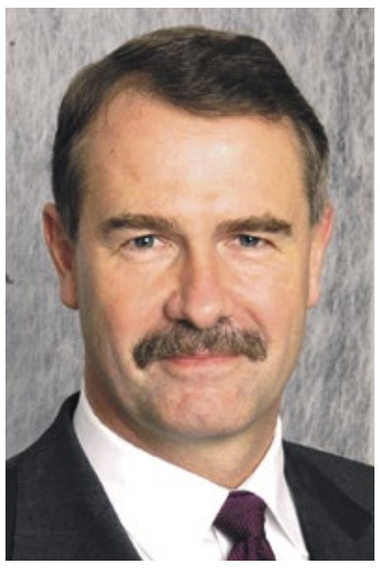
Refreshing Chemical Distribution

Azelis Sets Out to Drive Future Growth Plans with a Different Way of Doing Business

Development and Growth – At the end of April, specialty chemicals distributor Azelis, which has an annual turnover of €1.1 billion announced that it had successfully secured a refinancing package for a further three years. In addition the company's main shareholder, private equity investor 3i, has provided further equity support of €10 million. The deal that provides Azelis with strengthened liquidity and financial resources reflects exceptional support from the banking community and from 3i for the business plan proposed by the new management around Dr. Hans-Joachim Mueller. The former executive at Swiss specialty chemicals group Clariant and German chemical company Süd Chemie became CEO of the Azelis Group a year ago. CHEManager Europe's Dr. Michael Reubold spoke with Dr. Mueller about what the new leadership team has achieved so far and about his strategy to further develop and grow the business.



Dr. Hans-Joachim Mueller, CEO, Azelis Group

CHEManager Europe: Azelis has gone through some restructuring. What are key changes that have been made, recently?

Dr. H.-J. Mueller: I wouldn't call it restructuring because that sounds as though we were only cutting costs, which was not our prime focus: This is most definitely to generate profitable growth. Azelis was established in 2001 and over time has grown rapidly through acquisitions bringing together over 37 specialist distribution companies.

In 2008, new management was brought in to build one streamlined organization, a one-brand Azelis value system and a common ERP platform. During this process a number of internal activities were started. However, when you do this, quite naturally you can lose sight of external factors; thus our market focus was maybe not as good as it could have been. So at the end of 2012 a new management team was brought in — Laurent Nataf as the COO, Martin Hollenhorst as the CFO, and myself. We were entrusted to take Azelis to the next stage of its development by building on what was already established and to push more strongly into the markets we serve. We aim to improve our offering to customers by fostering relationships with existing principals and forming sustainable relationships with new principals.

Have you changed your market approach in terms of the product portfolio you offer or the market segments you address?

Dr. H.-J. Mueller: No, there are still two markets we address. On one side, there is the chemical industry with segments like coatings, additives or homecare and cleaning. On the other side is the life sciences industry where we are active in pharma, food and health, personal care and to a lesser extent, animal nutrition. So here we didn't restructure, to use that word, as an effective market driven organization already existed. What we did do though, was to better adapt our set up to deliver on growth objectives: we focused on developing a clear-cut strategy and securing refinancing to ensure that we have the means to really grow in these markets in the years to come. So our prime focus for the first couple of months was really refinancing.

After you successfully accomplished the refinancing, you then focused on the strategy?

Dr. H.-J. Mueller: Yes, after winning the trust of the lenders, we started to develop a strategy that will allow us to offer what we internally call the lateral value chain to an industry. Offering a lateral value chain portfolio from A to Z into a market enables one-stop shopping for our customers and also demonstrates to principals that we are generating a pull. This is what we have addressed strategically: identifying the principals we need to develop further, and knowing the principals we need to get on board, to be even stronger along this market driven lateral value chain.

Why do we want to have that? As the company is geared for growth, we have well defined growth objectives with clear-cut responsibilities on who is driving the business from a financial point of view: this takes place in the countries because in distribution, where we aim to add value and be close to customers, we must have local managers in a country who run the business. Over and above that, we have additional personnel who oversee and drive principal development. These are key people for business generation who have close interactions with our principals and with Azelis' managing directors in the countries.

Speaking of countries, will this new strategy also increase Azelis' geographic footprint?

Dr. H.-J. Mueller: Definitely, we will further build on what we have in Europe and also expand our reach into Asia. As we speak, we are active in India, have a fast-growing representation in China and an established presence in Japan. Next we will roll out our activities into Southeast Asia by establishing three, maybe four new distribution centers within less than two years. That doesn't mean that we will stop investing in the countries where we are already established, but vast countries with several regional languages like China or India, just cannot be served from one office.

For instance in China, in addition to our headquarters in Shanghai, we have representations in Guangzhou in the south and in the Chaoyang District of Beijing in the north. We will also be rolling out into the west of China, because we believe there is extensive untapped potential for distribution there.

In India we will also add more offices as we are currently only represented in Mumbai. But we also need to be in Delhi and in Hyderabad, and will consider having a representation in Trivandrum, Kerala. This is our role as a distributor, as a partner for our principals, to channel their products into every corner where there is a potential buyer.

Do you also look into other geographies like the Americas?

Dr. H.-J. Mueller: We certainly do look into these markets, however, not with the strategic ambition to address them within the next two to three years. The distribution industry, and this obviously has something to do with how it was primed, is very much opportunistic driven. As there were so many opportunities in the past, companies' cherry picked and there was no real need to have a rolled-out strategy.

I strongly believe though, that the time of just "going with the flow" is gone. You need to have a clear-cut strategy to decide what you want to accomplish and where you want to go. In Latin America, even though these are very attractive economies, there are several people already playing. The same applies to the U.S.: we have a representation in Canada, which is doing well, but going into the U.S., which is the most mature distribution market for chemicals you can think of, is not somewhere we would really enter into at this time.

After Southeast Asia we are considering to move more into Africa. Although the African market is still very fragmented and distribution is difficult, we have seen good growth rates in economies like Angola, Kenya and Nigeria in the last couple of years. So we will further determine whether it makes sense for us and for our partners to be represented in those countries.

Does the refinancing give you a solid basis for these future investments and expansions?

Dr. H.-J. Mueller: Absolutely. The whole refinancing was done in light of what we are trying to accomplish. We explained to our lenders what we planned to do and then outlined what we needed to get there. We were able to secure all the necessary funds in that refinancing so we can take the necessary steps for a successful future for Azelis, centered on helping our principals to grow in the markets we serve.

> *We develop new ways to create value for our partners.*

Having worked for chemical producers in the past you know both sides of the fence. What are the success factors of a good relationship between a chemical distributor and a chemical producer?

Dr. H.-J. Mueller: The essential success factors, like almost everywhere in life, are openness and trust. As a chemical distributor, we have to align our strategy with the strategy of our principals, which we do on a regular basis. This sometimes can be a little bit of a challenge because different principals can have varying strategies and we need to amalgamate them into one approach that satisfies the ambitions of all. That said, overall our partners have the ambition to grow, so for us this is the common denominator and the basis of a relationship that creates value for our partners.

At the Fecc annual congress, delegates discussed the role of distributors in driving innovation in the supply chain. How do you see this role?

Dr. H.-J. Mueller: Outsourcing into distributors is growing in the chemical industry. And that is partly because the face time chemicals producers have with smaller B, C and D customers — sometimes even with A customers — is diminishing. So when you don't have direct customer contact, where do you learn what the market wants to have tomorrow? Distributors facilitate a really close interaction between the principal and the customer. We are well placed to hear about a future trend in a certain market which we can then encourage our principal to embark upon.

On top of that, at Azelis we are continually adding to our suite of labs located worldwide, to carry out formulation work for customers. This is another value-added service which is strongly pushed within our group. As we represent different products from various principals we can do things a manufacturer cannot do: we can promote adjacent products because our chemists and chemical engineers have the expertise to develop inventive formulations.

So firstly, we can help our principals learn what the trends are and secondly, we are able to ensure that their products are embedded in formulations that are then offered to customers. This is a service very much appreciated. We develop new ways to create value for our partners, and through our experienced people we introduce fresh ideas and innovative products to benefit both our customers and principals. Thus, we believe that we have a refreshing approach to chemical distribution.

Would you say that for distributors, who usually don't have product brands and production facilities, the most important assets are market knowledge and the skills of your people?

Dr. H.-J. Mueller: It is most definitely our people. They are the real asset of a distributor. As said, we don't have any production facilities, so we need to make sure that the assets we offer to our partners are value-added, relevant and appreciated. And this is very much what we do have in Azelis, an understanding that our value is in our knowledgeable people.

In the past "think globally, act locally" was the formula for success for chemical distributors. Is that still true or do you think that meanwhile there are other requirements and success factors?

Dr. H.-J. Mueller: I think the statement as such is still very much true. But there is a different facet that needs to be taken into consideration. Clearly you always sell locally. However, when it comes to knowledge and expertise, we also need to have a more global approach. For example, when we represent a principal in one country and the same principal also entrusts us his business in another country; our customer-facing people across a market can interact and exchange their views on the USP of the product and how to best position it. This in turn results in more rapid market penetration, hence a clear advantage in having this global perspective. This is also the prime driver I believe for expanding our geographical reach.

Do you think that consolidation in the chemical industry among the producers of chemicals also affects the chemical distribution industry? Do you see more challenges from that or more opportunities for your company?

Dr. H.-J. Mueller: Certainly, when you consolidate as a producer and reach the critical mass that allows you to have the lateral value chain in-house, then you may be tempted to move more away from distributors. And yes, consolidation in the chemical industry is going to continue, because when you look on a global scale, this is still a very, very fragmented industry. Having said that, I do not envisage this to be disadvantageous for us within the next 20 to 30 years. There is still a great deal of innovation taking place in the industry, not necessarily coming from the biggest firms, but also from those challenging. There are many smaller firms coming up with new, game changing technologies. So I do really believe that there is great potential for the distribution industry.

bit.ly/chem-distribution

Hidden Costs of Broken Supply Chains

Tariffs are No Longer Biggest Barrier to Cross-Border Trade

In The Red Tape – For decades, governments and companies around the world focused almost exclusively on tariffs as the biggest impediment to global trade. Today, tariffs are at a 30-year low, but trade remains seriously constrained.

The chief culprit? The many inefficiencies, chokepoints and nontariff barriers that hobble global supply chains and increase the costs of trade. Companies ignore these barriers and costs at their peril.

Many corporate leaders know of these obstacles from direct experience. For example, one diversified chemical company exports acetyl and other products to the United States. It needs approvals for every shipment from as many as five U.S. regulatory agencies. The requirement delays 30% of inbound shipments, often causing cancellations from customers who are fed up with waiting.

How significant are such barriers overall? Bain & Company, in collaboration with the World Bank, analyzed the business implications of nontariff supply chain barriers — everything from border delays and inconsistent product regulations to poor infrastructure and rampant corruption. The analysis demonstrates that reducing even a subset of these obstructions could bring about an increase in global gross domestic product that is six times greater than the potential increase from removing all tariffs.

These findings have broad, long-term implications for policymakers: They suggest that governments need to refocus efforts on creating supply chain efficiencies if they want to truly unlock the economic potential of global trade. For companies operating in international markets, the message is more immediate. Making the right choices about where and how to deploy assets globally requires full understanding and analysis of how supply chain barriers affect return on investment. Failing to anticipate the costs and risks involved can wipe out the business advantages of sourcing, operating or selling in foreign markets.

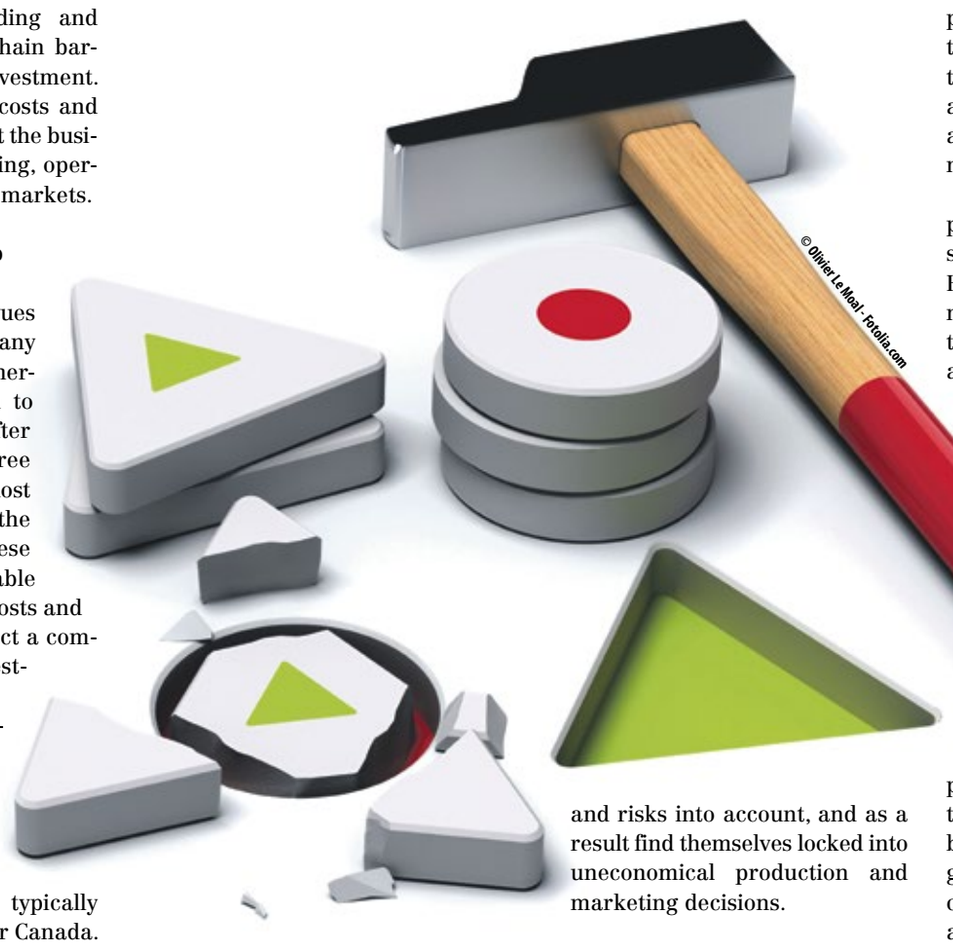
Moving Production To Mexico

Over the years, my colleagues and I have worked with many companies weighing the merits of moving production to Mexico, particularly after the North American Free Trade Agreement ended most formal trade barriers on the continent. In doing these analyses, we have been able to quantify supply chain costs and understand how they affect a company's real return on investment.

The benefits of investing in Mexico are well-known. Hourly wage rates are about one-fifth of those in the U.S. Capital expenditures related to building facilities are typically 10% less than in the U.S. or Canada. Certain products — nonperishable items with high labor content and high value-to-weight ratio — are particularly well-suited for production in Mexico.

A thorough analysis, however, turns up a number of hidden costs (fig. 2). Mexico's lack of federal and provincial tax breaks can add 1% to investment costs up front. The lower productivity of Mexican hourly workers coupled with a lack of automation means that a company might have to boost staffing levels 25%, erasing some of the labor-cost advantage.

Transporting goods in Mexico is also a problem. Gaps in road and rail connections require shipments to travel extra distances, eating into margins. Safety is a consideration as well. High crime rates in Mexico might require a company to take extraordinary measures to safeguard both its facilities and its goods in transit — putting armed guards on all trucks, for instance. Security measures alone can boost fixed costs by as much as 7% per year.



Many companies have profitable operations in Mexico, and it might make sense for a manufacturer to establish a beachhead there. But the key to all such decisions, regarding Mexico or any other country, is to take a full accounting of all the relevant costs and potential supply chain inefficiencies.

For instance, will delays force a company to stockpile buffer inventories, tying up working capital and adding to direct costs such as warehousing? If so, what risks follow in the form of depreciation, spoilage or production bottlenecks? Companies often fail to take these costs and risks into account, and as a result find themselves locked into uneconomical production and marketing decisions.

Finding Hidden Costs

Supply chain barriers to trade are both complex and widespread. A comprehensive approach to foreign investment decisions means recognizing costs in four important categories of the supply chain. Executive teams can begin by asking some key questions relating to each category:

Market access. How many regulatory agencies will you have to deal with as you move goods into or out of your chosen market? What are the licensing regulations that apply to your product or service? Are there preferential rules or regulations that give local companies an advantage in the market? Will that affect your costs or competitiveness?

Border administration. What percentage of shipments will be inspected at the border, on average? How does that compare with other markets? What is the typical delay time at a particular border or port, and what will that cost in terms of spoilage, theft or the need to stockpile additional inventories? How often do border officials demand "facilitation payments" to move goods efficiently? Are you prepared for the repercussions of not paying, including potentially severe delays?

Telecom and transport infrastructure. Does the country have an electronic system at the border allowing shippers to declare goods in advance, speeding up processing? Are those systems reliable and used consistently? How fast on average are trucks or rail shipments able to move to and from key ports? What are the common delays and how costly are they? What special fees, licenses or other regulations do local authorities impose on truckers that add costs or slow the movement of goods?

Business environment. What are the political and administrative realities in your chosen market, and how will that affect the ease and security of doing business there? Do businesses enjoy the support and encouragement of government officials, or is there a history of random taxation, excessive fees or other attempts to extract value from the private sector? Are the rules and regulations that pertain to your business clear and consistent? Are there established procedures for working through them?

All of these costs can be estimated to gauge the effect on potential investment returns. But if your team can't provide definitive answers to questions like these, moving forward can have real repercussions.

Global trade has increased sharply in the past 30 years, and the opening of markets long considered inaccessible has created rich opportunities for companies of all sizes in every industry. But the companies that get it right are the ones that identify and analyze the real cost of capturing the opportunities — and that avoid the mistake of going in unprepared.

In-depth graphics for this article can be found online.

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Challenges in Healthcare Industry

Pharma Logistics Expert Movianto Provides Solutions

CHEManager Europe: What major trends do you see in European healthcare and logistics?

M.Steensen: The European healthcare market is, as many other industries, facing major challenges. Due to the financial crisis and cuts in healthcare spending, we are seeing a lot of consolidation in the form of mergers and acquisitions. Consequently, customers require easy access and consistency in quality across the whole of Europe, as operations here can be quite complex. Other segments within the healthcare industry, such as regional hospital distribution centers, are also looking to outsource their supply chain to professionals.

What is Movianto's current situation?

M.Steensen: Due to growing demand, our customers in the healthcare industry require truly specialized and centralized logistics service providers. Movianto was recently acquired by Owens & Minor. This proved to be an excellent opportunity to merge Owens & Minor's capabilities in traditionaldistribution of branded medical supplies with Movianto's strength in pharmaceutical logistics. The two cultures come together and thrive as a result of the strengths of each, based on organizational alignment to customers' requirements.

Marina Steensen, commercial director, Movianto

Where is Movianto heading strategically?

M.Steensen: Many years of success in providing local solutions have made us a truly pan-European provider of logistics in branded medical supplies for pharmaceutical and healthcare customers. Through processes such as restructuring our accessibility and centralization, we are expanding our extensive European coverage, as well as improving our accessibility for customers on a European level, all while continuing to put value to the local expertise our teams have.

What is your main aim as Commercial Director for Europe?

M.Steensen: Movianto should be top of mind for healthcare companies requiring the logistical solutions which we offer and develop together with customers. And it is my job to create the conditions to allow our teammates to give our customers the best-possible service in this competitive environment. Furthermore, the European sales team coordinates with teammates across Europe in order to make us even more successful.

What new services will you be offering to clients?

M.Steensen: Our branded medical device services are new, heavily supported by Owens & Minor. Our European Distribution Center in Oss, in the Netherlands, has recently been certified with the important ISO 13485 standard. Value-added services are adapted to each client's needs – labeling, kitting and repacking, postponement and more. Important to say is that we work with our customers in meeting the challenges in the supply chain in an ever changing environment.

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Europe's Largest Chemical Cluster

Antwerp Continues to Invest in Chemical Industry

Gateway For Major Players – With 40 square kilometers of chemical industry housing the world's major players, the port of Antwerp may rightfully call itself the largest European chemical cluster. Its central position with easy access to both German and French industrial hot spots and major local production of chemicals make Antwerp an attractive facilitator for chemical companies worldwide. With continuous investments, the port of Antwerp keeps improving its capacity, with proper respect for safety and the environment.

Leading Chemical Companies

Seven of the world's top 10 chemical companies have their plants here. Significant investments are undertaken by the likes of majors such as BASF, Total, Kuwait Petroleum, Lanxess and Evonik. These companies keep their plants in Antwerp competitive and at world-class efficiency levels.

Deep-Sea Traffic in the Heart of Europe

Right in the center of the continent of Europe, the port of Antwerp continues to thrive. Its location is ideal because of the many industrial sites at relatively short distances, which is of course very advantageous for transportation of chemicals. The port also has easy access for deep-sea ships. It can receive Triple E Class container ships and Class LR2 tankers. Its central position and easy access combined with a dense foreland and hinterland network make the port of Antwerp a great partner for the chemical industry.

Largest Chemical Storage Capacity in Europe

The Port Authority and the private sector have invested and continue to invest strongly in expanding the capacity of the oil and chemical sectors. As a result, maritime transport for tank storage companies has grown by 151% in the past 10 years. Over the same period the number of tank storage terminals has risen by 40%, to 15, while the total tank storage capacity has doubled to 6.3 million cubic meters. The port of Antwerp has Europe's largest storage capacity for the petrochemical industry, with nearly 350,000 cubic meters of stainless steel tanks and eight multi-customer plastics terminals with a total storage capacity of more than 430,000 cubic meters. All these terminals operate to the highest standards (Safety, Security, Health, Environmental care and Quality — SSHEQ) for storage and value-added activities.

Important Nodal Point of European Pipeline Network

The port of Antwerp is the most important nodal point for the West European pipeline network. Pipelines offer a safe, reliable and environmentally friendly means of transport for the oil, chemical and energy sectors to supply and distribute their products in Belgium and neighboring countries.

Within the Antwerp chemical and petrochemical cluster, the manufacturing and tank storage companies are connected by more than 100 different product pipelines: Nearly 1,000 kilometers of pipelines transport about 90% of the liquid products within the port.

Antwerp, the largest producer of ethylene in Europe, is connected to the ARG network that supplies all the ethylene to the chemical industry in Belgium, Germany and the Netherlands.

From Antwerp there are numerous pipelines to Terneuzen, Rotterdam, Feluy and the Rhine/Ruhr area.

The relatively short delivery distances within the port of Antwerp,

together with the huge pipeline network, ensure fast, safe and environmentally friendly transportation. This correlates very well with the requirements of the chemical companies under their Responsible Care scheme.

Value-Added Logistics

Players in the port of Antwerp offer extensive value-added activities such as breaking bulk and transferring containerized cargo to all possible formats and sizes, blending, tolling, labeling, heating/cooling, grinding, quality and quantity control, temperature-controlled warehouses, vendor-managed inventories, transport and distribution, etc. The port of Antwerp favors an open and competitive offer in logistics for chemicals in all stages of the value chain, tailored to the customer's needs.

Goods are handled with efficiency and care, offering a high-quality service.

Combining Speed And Quality

The tailored handling of chemical products doesn't slow down the transit of goods through the port in the least. The high productivity of dock labor, the port's accessibility for the very largest container and bulk carriers and the extensive quadri-mode connections with the hinterland mean that the stay in port is very short.

The logistics service providers active in the chemical sector are world-renowned companies recognized for their high productivity and their innovative, flexible, customer-oriented, no-nonsense approach. The close connections with the largest chemical cluster in Europe ensure that customers in this sector enjoy state-of-the-art facilities and a wide range of value-added activities for packaged chemicals.

Continuous Investments

The port leads not only in size, but also in innovation matched with all necessary investments, both private and public.

The three largest oil refineries in the port of Antwerp — Gunvor, Total and ExxonMobil — together are investing billions of euros in their Antwerp sites. BASF is building a butadiene extraction facility (for more than €100 million), expanding its cyclohexanone capacity (for about €10 million) and investing in additional berthing facilities for unloading seagoing ships and barges (tens of millions of euros). Lanxess is expanding the capacity of its glass fiber plant (€15 million), starting up two pilot plants for developing environmentally friendly chemical bands and investing in a new polyamide plant that is due to become operational in early 2014 (€75 million). FRX Polymers is building a new production unit for a fire-resistant polymer (€20 million). Evonik Degussa is expanding the capacity of its methionine and MTBE production plants and is building additional facilities for producing butadiene. As a consequence of this investment, the neighboring company Oiltanking Stolthaven Antwerp will invest in additional facilities. Ineos Oxide has built a new ethylene terminal. Kuwait Petroleum International is modernizing its lubricating oil plant (€63 million). Sinopec has acquired a 50% stake in Vesta Terminals with the intention of further expanding it. Ferro expands its plasticizer product line by investing in dibenzoates manufacturing capacity. Praxair will build its second air separation plant expanding its production capacity of industrial gases. Praxair also announced its investment in the extension of its pipeline system in the port of Antwerp. Indaver-MediPower is building a facility for environmentally friendly processing of medical and sensitive waste.

The port itself also continues to make significant investments. One of the major ongoing projects is LNG-fueled traffic. Barge LNG bunkering has been available since 2012, and Antwerp plans to have ship-to-ship bunkering ready by the year 2015. The port of Antwerp leads the International Association of Ports and Harbors' (IAPH) workgroup on LNG-fueled traffic.

Expertise Group

To further develop this growth potential, the Antwerp port community has set up an Expertise Group focusing on value-added activities for packaged chemicals. Experts from the Port Authority and specialist private companies examine ways in which the logistics handling of packaged chemicals can be further improved. By bringing the port's strong points further into line with the requirements of the chemical sector, better use can be made of the port's existing advantages. The Expertise Group also acts as a sounding board for the Port Authority for the purpose of developing a proactive strategy aimed at expanding the port's market share in this sector in a sustainable way.

Growing In Difficult Times

Figures show that between 2000 and 2011 the total deep-sea traffic for petroleum derivatives increased by nearly 50%, and maritime flow of liquid bulk for chemicals has more than doubled. When we look at the evolution of cracking from 1973 until today, volumes have increased from 3 million to 10 million tons. In 1973 there was still no desulfurization. Today the port of Antwerp has 36 million tons of desulfurized product a year.

It's clear that even in today's difficult times the port of Antwerp remains one of the best locations in the world for the chemical industry. It benefits greatly from continuous investments, its strategic location and comprehensive logistical services.

The port has confidence in the future and continues to invest to remain a key partner for the European chemical industry.

For in-depth graphics and more photos, please see the article online.

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bit.ly/Antwerp1

Standardized Tests

SQAS Has Assessed Logistics and Distributors for 21 years

Streamlined System – The chemical industry in Europe utilizes to a large extent the logistics services offered by third parties to store, handle and transport raw materials, intermediates and finished chemical products. The chemical industry also partners with chemical distributors as an essential route to certain customers.

Chemical companies need assurance that these operations are carried out in a safe and high-quality manner with due regard for the protection of employees, the public and the environment. In the past, this assurance has often been obtained by individual chemical companies undertaking periodic audits of their logistics service providers and distributors, leading to a fragmented approach and a multiplicity of auditing programs, which was costly and inefficient for the chemical, transport and distributor industries.

SQAS Basics

In 1992, the first trials of a pioneer system to assess haulers were carried out. Twenty-one years later, the Safety and Quality Assessment System (SQAS) has obtained wide acceptance in standardizing assessment procedures for logistics service providers and distributors of the chemical industry in Europe.

SQAS provides a tool to assess the quality, safety, security and environmental management systems of logistics service providers and distributors in a uniform manner by independent assessors, using a standardized questionnaire. SQAS helps chemical companies in the process of selecting logistics service providers or distributors and in defining improvement actions with each of them.

An SQAS assessment by an independent assessor does not lead to a certificate but results in a detailed factual report, which each individual chemical company needs to evaluate according to its own requirements.

SQAS includes five modules that can be combined to cover the different activities of the company to be assessed: transport service, tank cleaning stations, warehouses, rail operators and distributors (called ESAD).

Growing Population

A total of 814 assessments were made under SQAS and ESAD in 2012, a record number with increases seen in Spain, the Netherlands and the UK. By the end of 2012 there were 2,308 active reports in the SQAS database, of which 1,319 came from transport companies and more than half the remainder from cleaning stations. There has been a sharp increase in the number of warehouses being assessed under SQAS in recent years, with 170 such facilities active in the database at the end of 2012. There is still a growing trend, and another record in the number of SQAS assessments is expected by the end of this year.

Support from the Chemical Industry

There are now 44 chemical companies supporting and using SQAS, as well as 18 chemical companies using ESAD. Ninety-five logistics companies and chemical distributors are part of the Logistics & Distributors (L&D) User Group, which all have access to reports of other logistics companies when those reports are authorized for release. Participation in the L&D User Group is open to any transport company or chemical distributor that has been assessed under SQAS or ESAD.

And it is not only logistics service providers who are being assessed. In March of this year the European Chemical Industry Council (Cefic) undertook a survey about the quality of its assessors. A questionnaire was sent to 93 assessed companies, randomly selected, of which 36 responded. All of them rated the assessors as good or excellent. The survey will be repeated again before the end of this year.

New versions of two relevant documents related to the SQAS system were issued this year: The SQAS/ESAD 2012 Guidelines and the SQAS Accreditation Manual. The first document explains the main features of the SQAS system and the second the rules for candidates to become SQAS assessors and to maintain their accreditation. The documents can be downloaded from the SQAS website.

Checking L&D Performance

Cefic has calculated the average "yes" score for each subsection of the different SQAS modules (transport service, tank cleaning, warehouses, rail operators and distributors) and there is some consistency in those that have the lowest scores. In broad terms, they deal with service partners and contractors, security, and the use of behavior-based safety programs. Risk assessments and management review are important areas for improvement in tank cleaning stations. For chemical distributors under the ESAD assessment, issues such as community interaction, product stewardship of food products and the transport of unpacked food products are aspects to improve. It is notable that Cefic itself is addressing some of these issues by issuing guidelines jointly with the European Chemical Transport Association (ECTA) on, for instance, behavior-based safety and loading/unloading procedures.

The SQAS website allows the user to carry out statistical analysis and generate meaningful data to find out areas of improvement. The most significant value in such analysis is that it allows all assessed companies to benchmark themselves against industry at large. Each company can see exactly where they lag behind the industry average and, where there is not a good reason for such divergence, can target its resources toward improving its performance. Each SQAS user can simultaneously compare up to 15 assessment reports, whether they refer to subsidiaries of the same company or different companies.

SQAS in the World

SQAS is also breaking out of its European bounds and being taken up by chemical trade organizations in other parts of the world. Local versions of SQAS have been introduced in Brazil, South Africa and China. Cefic manages SQAS in Europe and it is supporting the development of similar systems in other parts of the world.

Cefic is currently helping Gulf Petrochemical and Chemical Association (GPCA) to develop a SQAS system in the Gulf Area.

An important part of SQAS, as with all initiatives deriving from the Responsible Care program, is that it should drive continuous improvement in safety and quality standards. As such, it is inevitable that SQAS will develop over time. As long as chemical companies continue to use it as a source of information to improve their knowledge of their logistics service partners, it will continue to be a major element in the ongoing process of improving safety standards in the transport of chemicals, on a global basis.

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New versions of two relevant documents related to the SQAS system can be downloaded here.

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Pharma

Camelot's Pharma Radar shows limitations of biosimilars.

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Pharma Packaging

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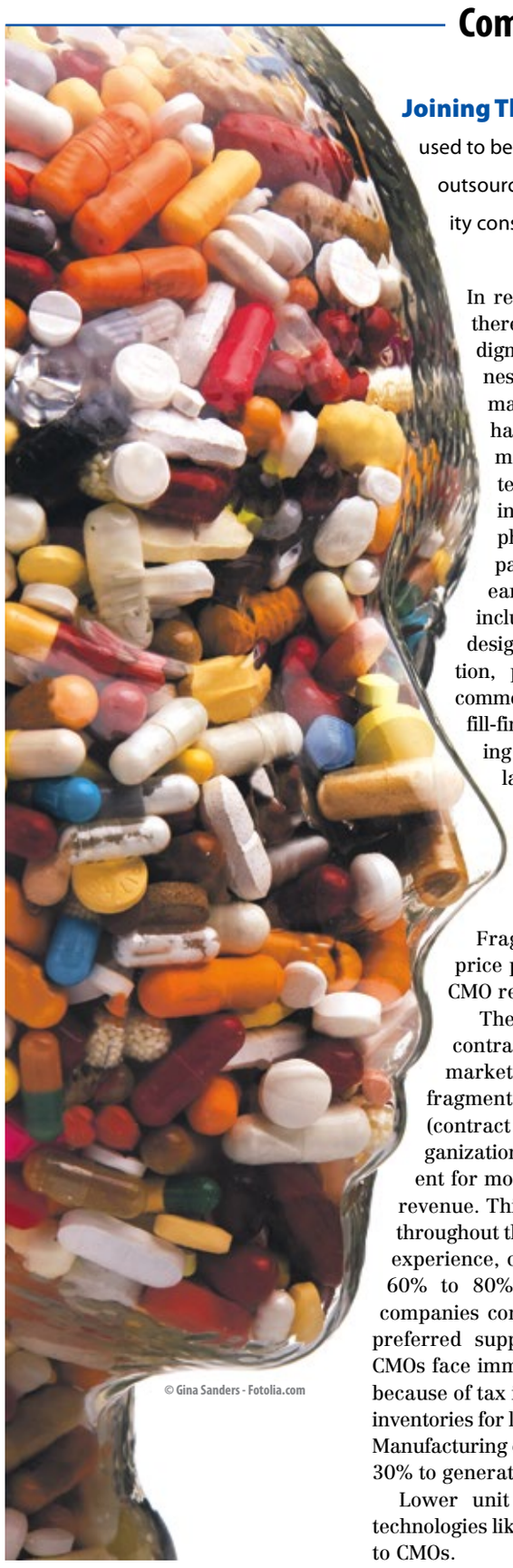
Expanding CMOs

Companies Aim to Stand Out in Global Pharmaceutical Contract Manufacturing Market



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Joining The Supply Chain – Pharmaceutical contract manufacturing used to be viewed as a one-off activity where a pharmaceutical company outsourced a drug for manufacturing predominantly because of capacity constraints.

In recent times, however, there has been a paradigm shift in the business model of contract manufacturers. They have gone from one-off manufacturing to integrating themselves into the supply chain of pharmaceutical companies, right from the early-stage activities, including preformulation design, process optimization, preclinical stage to commercial manufacturing, fill-finish services, packaging and logistics, regulatory, analytical, and marketing support.

Challenges of the Existing CMO Business Model

Fragmented market and price pressure drive down CMO revenues.

The pharmaceutical contract manufacturing market remains highly fragmented, with many CMOs (contract manufacturing organizations) relying on one client for more than 50% of their revenue. This suppresses prices throughout the industry. Based on experience, cost and size, nearly 60% to 80% of pharmaceutical companies consider going back to preferred suppliers. Furthermore, CMOs face immense price pressure because of tax incentives and lower inventories for low-volume products. Manufacturing costs must drop up to 30% to generate tax savings.

Lower unit volumes and new technologies likely will pose a threat to CMOs.

Low-volume products such as niche products, orphan drugs and generics as well as emerging markets present poor profit margins and lower inventories for CMOs, thereby resulting in price pressure and increased competition. The existing CMO business model can address only the basic requirements of global pharmaceutical companies such as unit cost, technology, IP protection, cost flexibility, and security of supply. This model does not cater to the restructuring costs (compensation arrangements and disposal of old facilities), financial effects (tax implications, government subsidies and exchange rate exposure) and commercial demands (local market approvals, portfolio and brand).

Lack of venture capitalist (VC) funding for early-stage companies will result in lower expenditures than prerecession levels.

A majority of VC firms prefer investing in companies with promising late-stage (phase II and phase III) drug candidates than in early-stage companies. The United States and Asia seem to be more attractive targets for VC firms than Europe, as Europe has been comparatively slow in regaining financial stability. In 2011, pharmaceutical R&D spending decreased for the first time in more than a decade in major markets such as the United States. Overall, VC investments in the pharmaceutical contract manufacturing market seem to be on a declining curve over the next five years as investors back away.

Injectable-Dose Formulations Likely to Spur the Growth of CMOs

Despite the current dominance of solid-dose formulations, injectable-dose formulations have experienced strong growth in the past five years, with a compound annual growth rate (CAGR) of 18.7% from 2007 to 2012. The significant growth for injectable-dose formulations is expected to continue in the next five years attributed to the following key factors:

The highly sterile and aseptic conditions and skilled personnel required for manufacturing injectable-dose formulations fuel demand for outsourcing as it appears to be a viable alternative to additional manufacturing capacities for pharmaceutical and biotech companies.

Cytotoxics are expected to be the key growth driver for the injectable-dose formulations segment because of the robust demand for oncology and other high-potency drugs such as antibody conjugates, steroids and IV fluids that require quick onset of action.

Pharmaceutical and biotech companies prefer prefilled syringes for existing and new products as prefilled syringes eliminate issues with overfilling of expensive drugs, thereby resulting in significant cost-savings. This likely will be a major driver for outsourcing to CMOs.

Other factors driving the growth of the injectable-dose formulations segment include rapid onset of action, better therapeutic efficacy and greater return on investments to manufacturers.

Unmet Market Need	Potential Game-Changing Strategy
An integrated, end-to-end business model on a risk-sharing basis with clients	Increased focus on preclinical development services such as formulation development, process support, process development, clinical trial manufacturing, analytical service and regulatory support in addition to the core custom manufacturing services is necessary to integrate into the value chain at early life-cycle stages and to build long-term relationship with clients. To attract more clients, certain CMOs likely will adopt a differentiation strategy that includes repositioning themselves among clients by promoting more services such as formulation improvements, alternate dose formulations, real-time order tracking, and logistics support. Patheon and DPT Laboratories have been two such leading CMOs that have positioned themselves as development service providers capable of transitioning from offering clinical services to commercial manufacturing.
Instilling new capabilities and anticipating capacity demand for careful outweighing of benefits and risks	Industry consolidation by means of acquisitions and strategic alliances to expand capabilities in new product and service segments as well as new geographies has made Aenova one of the fastest-growing companies. Aenova's foray into the liquid and semi-solid dose formulations segment by the acquisition of the Temmler Group in 2012 has resulted in a significant increase of market shares and capacities to meet global demands.
Demand for next-generation biological therapies such as vaccines, anti-cancer therapies, gene therapies, specialized antibiotic treatments and recombinant proteins	Because of increased focus of big pharma companies on biologics to address unmet needs in therapeutic areas such as oncology, the injectable-dose formulations segment — which is a low-volume, high-margin business — will likely be the growth driver for CMOs. Key focus areas in sterile manufacturing of injectable-dose formulations include vaccines, anti-cancer therapies, antibodies, gene therapies, specialized antibiotic treatments and proteins. Hence, investments and capacity expansions in injectable-dose formulations manufacturing will help CMOs, particularly the small and medium-sized, to grow and sustain their businesses in the market. Cytotoxics and lyophilized products dispensed as injectable-dose formulations are expected to be a significant source of revenue for CMOs; therefore, more contract manufacturers likely will develop these capabilities.

Unmet Market Needs and Potential Game-Changing Strategies

Given the challenges and complexities of the existing business model of CMOs globally, market participants must adopt potential game-changing strategies, both to address unmet market needs as well as to grow in the highly competitive global pharmaceutical contract manufacturing market.

Conclusion

Quality, timeliness and cost remain the top three factors in choosing a CMO. But differentiation strategies such as repositioning themselves among clients, capturing projects at early life-cycle stages and entrenching an integrated end-to-end business model are likely to pave the way for growth and sustenance in a market as highly fragmented and regulated as pharmaceutical contract manufacturing.

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A Shaky Platform?

Sourcing of Chemical Raw Materials for Pharmaceutical Industry

Monitoring The Supply Chain

– The globalization of chemical raw material procurement is presenting significant challenges to the pharmaceutical industry. Adopting basic good manufacturing practice (GMP) and environmental, health and safety (EHS) standards constitutes an important tool for reducing the inherent risks. Observation of the latter, in particular, is getting more and more important. A dilemma between financial objectives and ethical behavior is particularly obvious in China and India.

Introduction

In the early beginning of manufacturing active pharmaceutical ingredients (APIs), the situation was different from today. Take acetylsalicylic acid (aspirin) as an example. Aspirin was manufactured from simple and readily available chemical raw materials

Chemical raw materials were defined as organic chemicals that could be used in organic synthesis to manufacture APIs or fine chemicals.

Chemical Supply Chain in Pharmaceutical Industry

At the beginning of the last century, the main sourcing aspects for an API manufacturer with regard to its chemical raw materials were:

- Only a few chemical steps were necessary in order to manufacture the final drug.
- Organic chemistry was booming.
- Companies such as BASF, Bayer, Dow, ICI and Hoechst were expanding their technical capabilities and their business.
- Transportation of organic chemicals took place over short distances and was well-organized.
- Regulations for current good manufacturing practice (cGMP) were not established and were virtually unknown.
- Organic chemicals were commercially available and could be considered partially as commodities.

As a result of these six major developments, the term "supply chain" has become an integral part of the sourcing process in the pharmaceutical industry, too.

Having this new challenge in mind, the International Pharmaceutical Supply Chain Consortium Rx-360 was founded in 2009. Its mission is to enhance the security of the pharmaceutical supply chain.

Global Aspects for API Manufacturers

The situation for API manufacturers has changed dramatically within the last 20-30 years:

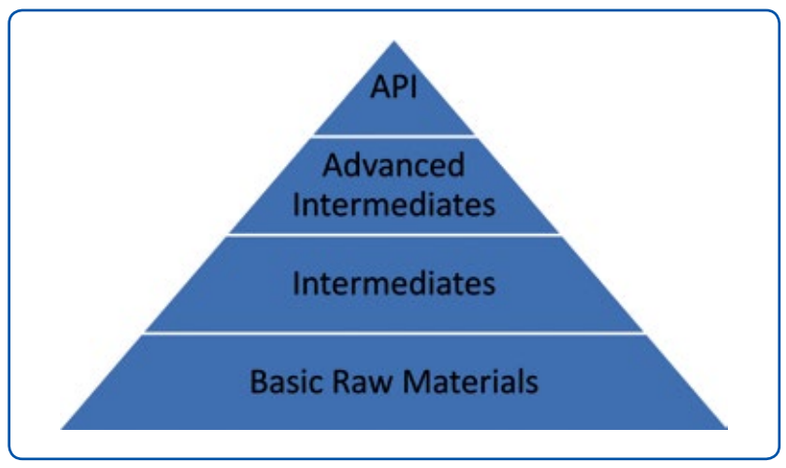


Fig. 1: Supply chain from basic raw material to API

- Many Western organic chemical companies closed their plants and companies in China and India entered this business.
- Transportation from Asia to Europe needs more time than transportation within Europe (e.g., sea transportation from Asia takes five to six weeks).
- Some other risks can be added: workers going on strike; natural disasters, such as earthquakes; political riots; arbitrariness of local authorities; insufficient protection of intellectual property rights.
- Clear communication is a must to avoid misunderstandings caused by culture differences.

As mentioned above, these shortcomings may drive the "total cost of ownership" into unfavorable dimensions.

Audits And Inspections

In the course of the sourcing exercise for API or advanced intermediates, quality audits are generally conducted according to ICH Q7A.

EHS (Environmental, Health and Safety) audit has been added lately to comply with the responsible-care principle. However, these EHS audits raise fundamental questions, namely checking for compliance with local regulations only or with Western standards? Should the audits be carried out by EHS specialists or purchasing generalists? Confronting with the deficiencies of the underlying philosophy raises a "conflict between (their) company´s ethic and its financial objectives," said Tony Scott of the European Fine Chemicals Group.

Examples of fundamental parameters — though not always mentioned in reports — are difficult to assess, for example:

- Qualification systems including design, installation and operation qualification (DQ, IQ and OQ).
- Process safety management: e.g., process design, process safety studies, determination of critical parameters, risk management studies.
- Qualification and training of workers.

Regarding the supply chain of, for example, a 10- to 15-step synthesis (e.g. Pradaxa, launched in 2012), a rough classification for the supply chain for the chemical raw materials can be made, as shown in figure 1: namely basic raw materials, intermediates (IM), advanced intermediates and the final API. Note: If the wording "chemical raw materials" or only "raw materials" is used, a clear definition is needed.

Advanced Intermediate And API

The regulated part of the synthesis begins normally from advanced IM. Advanced IM and the API have to be manufactured according to cGMP rules. These steps often will be manufactured by the pharmaceuticals company itself (in-house manufacturing) or by custom manufacturing (outsourcing).

It is acceptable that intermediates are produced under non-GMP conditions. The term non-GMP is misleading for several reasons. It should be replaced by basic GMP. Basic GMP is not officially defined, but it's a much better wording than non-GMP.

The big advantage of basic GMP: A thousands-ton-year that is used in the regulated part of the API synthesis, often following basic GMP requirements.

Basic Raw Materials

Basic raw materials are normally commercially available and usually not regulated. The chemistry behind it is, e.g., nitration, chlorination and fluorination of aromatic compounds. Nobody is really interested in any inspection of those "nasty" chemistries. What is more, even any "observation" is not easy to arrange, since these suppliers, as mentioned before, are located in Asia. Meanwhile, Western companies would like to get best pricing together with Western EHS standards. These two targets don't match.

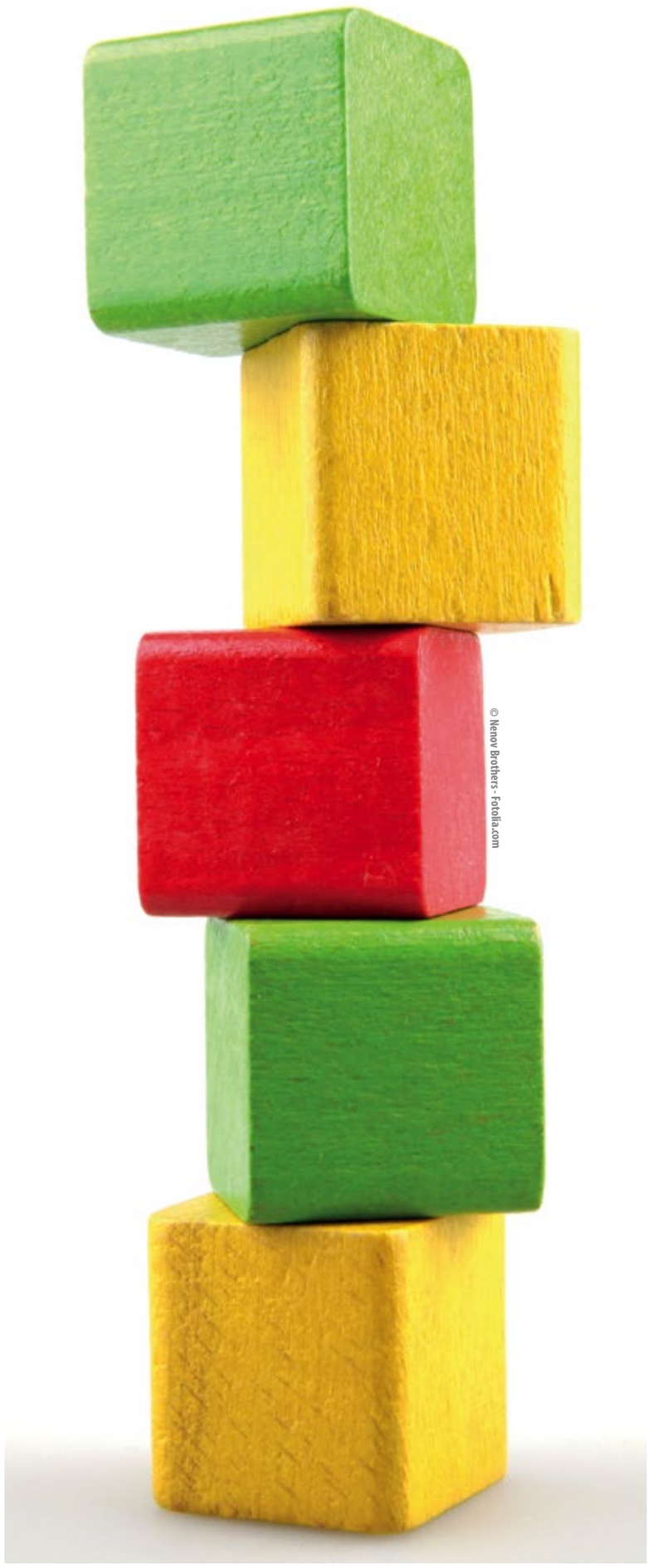
Purchasing people should bear in mind that the low price of the product often does not match with the chemistry behind it. Sometimes this is also a result of their target-setting and focusing on cost.

On the other hand, Big Pharma is facing serious cost problems once its top-selling originator drug becomes off-patent.

Packaging And Transportation

When sourcing chemical raw materials from Asia, further topics have to be clarified before ordering:

- Is a simple polyethylene bag suitable in case the chemical material is a solid?
- Does the material need to be protected against light and moisture?



- Is a fiber suitable as a secondary packaging material, or is an iron drum necessary?
- Can the drum be filled to its maximum? Half filling is a matter of waste.
- Are coated drums (or drums with inliners) necessary if the chemical material is a liquid? Can the liquid be solidified? Is the drum or inliner suitable when the material has to be melted before further use?
- Are all the required packaging materials available in Asia or do they have to be imported?
- Does the labeling meet international standards and internal requirements of the customer's company?

Pest control of the container, for example, sometimes is done before charging the material, but that is difficult to check. Storage of chemical materials at harbor for a long time can cause degradation. Thus analytical results from China and India may be different from those the customer gets after several weeks of transportation.

Conclusion And Outlook

Today's sourcing of chemical raw materials from phase I onward should be part of well-organized supply chain management in the pharmaceutical industry.

Fine chemicals are the most important category in the pharmaceutical industry, covering the line from basic raw materials to intermediates and advanced intermediates up to API.

Inspection of the manufacturer of non-cGMP products should be integrated in the supply chain. Instead of non-GMP, basic GMP (and basic EHS) requirements are defined and proposed and may become the basis in an inspection.

Price cutting by Western companies will create further risks, because basic raw materials manufacturers in Asia should get the chance to invest in better EHS standards. It would be much better to skip all extended EHS audits by Western companies and transfer this task to local authorities. Local authorities should have the biggest interest in establishing appropriate EHS standards. Corruption could be a hurdle, but it will be a better approach than a faked EHS inspection based on Western standards.

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Double Risk with an Upgrade

Business Development Landscape in Pharmaceutical Contract Manufacturing

Trial And Error – Despite a 150-year history and an aggregate R&D expenditure of $150 billion per year, innovation in the modern pharmaceutical industry is essentially still based on trial and error. Only one out of 5,000-10,000 investigated molecules will eventually be approved by regulatory authorities.

In total, fewer than 30 new medicines based on new molecular entities have been launched per year over the past 10 years. Moreover, during this period, one third of the new drug substances were high molecular weight molecules made by mammalian cell technology, which is accessible only to a small number of fine chemical companies. In the future, the share of biopharmaceuticals is expected to increase further.

The relationship between the pharma and the fine chemical industries is challenging. On the one hand, pharma is the major customer segment, accounting for almost two-thirds of the $85 billion fine chemicals market. On the other hand, the high attrition rate of the pharma R&D is such that the reservoir of attractive new product opportunities is small. The situation is exacerbated by the fact that the fine chemical industry is plagued with overcapacity and desperately needs to rejuvenate and expand its aging product portfolio.

Peter Pollak
fine chemicals business consultant, CMS Pharma

Andrew Badrot
partner and CEO, CMS Pharma

Probability of Success of the Pharmaceutical in Development

With a total size of 10,452 R&D projects in the pharma pipeline, the reservoir of opportunities for new business appears enormous — at first glance. Nonetheless, reality is different when taking into account the high attrition rate for new drugs. In preclinical development, more than 99% of the projects fail. Once in clinical development, the probability of success increases from 16% in phase I to 26% in phase II and 66% in phase III, to close to 100% after submission to the competent health authority authorizing the commercialization (fig. 1).

For the fine chemical industry, the high dropout rate in drug development across the various clinical phases is a major source of uncertainty for contract manufacturing organizations (CMOs) looking to rejuvenate their product portfolio. It is also the reason the CRAM (Contract Research and Manufacturing) strategy pushed by many Indian companies was not a particular success. It is based on the hypothesis that a backward integration to contract research generates business opportunities for custom manufacturing. In reality this is rarely the case, rather a strike of luck than a repeatable strategy.

Figure 1: New Drug Development — Probability of FDA Approval
Source: J.A. DiMasi & al., Trends in Risks Associated with New Drug Development: Success Rates for Investigational Drugs. Clinical Pharmacology & Therapies (March 2010) 87, pp 272-277

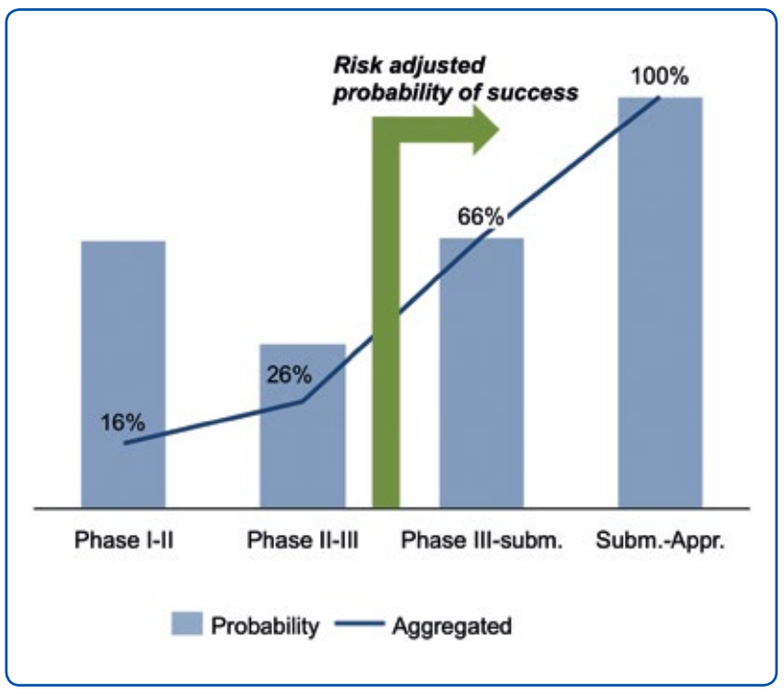
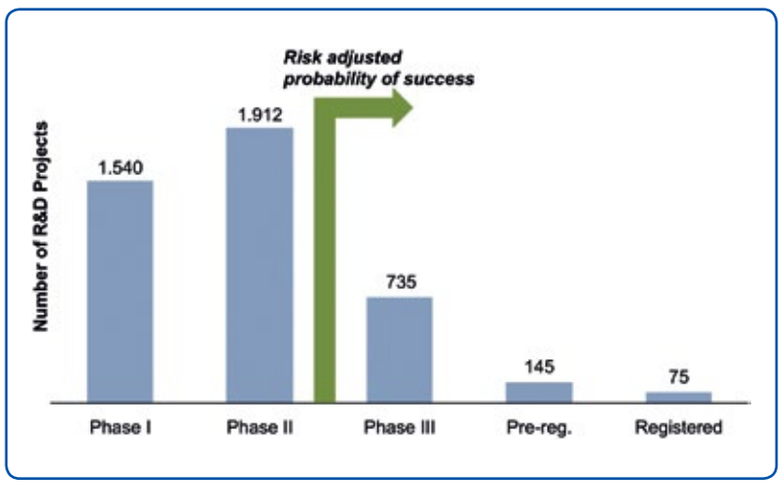


Figure 2: Size of Pharma Pipeline
Source: The Division of Science Resources (SRS) of the National Science Foundation; U.S. Institute of Applied Manpower Research, India (2011) 8. World Intellectual Property Report



Probability of Securing the Business

There are four points of entry along the life cycle of a pharmaceutical drug (figure 3) for a CMO to step in. At gate No. 1, samples of the new drug molecule are needed for in vitro tests. This business is not attractive because of the small chance of success and small quantities of active pharmaceutical ingredients (APIs) being produced. Therefore, it should be considered primarily as a promotional tool for acquiring a new customer. At gate No. 3, the FDA has approved the new drug for commercialization. However, at this point, suppliers have often been selected, and supply contracts have already been signed. Therefore gate No. 3 can be considered only if the price pressure on a product is increasing and there is a chance to submit an attractive offer, e.g., on the base of cost reductions achieved after development of a substantially more economical second-generation manufacturing process. At gate No. 4 the proprietary drug is approaching patent expiration and generic companies are preparing to enter the field. This gate is suitable for a fine chemical company involved in the manufacturing of API for generics.

For custom manufacturing projects, gate No. 2 is the pivotal decision point and requires close scrutiny. As drugs approach the completion of phase II-b clinical trials, several decisive events have taken place: the probability of getting approval for the drug now exceeds 50% while the volume requirements both for the drug product and drug substance are likely to take off rapidly. The procurement office of the pharmaceutical company gets involved. It determines the procurement policy, i.e., at which stage of the manufacturing process external suppliers will be chosen for both generics and exclusive products.

Requests for proposals have been dispatched to preferred suppliers as well as "niche" CMOs with the specific technical capacity and capability, while unsolicited offers are also received from interested fine chemical companies.

The key parameters for the selection of the contract manufacturer are the depth of the relationship between the pharma company and the CMO, the financial stability of the CMO and the attractiveness of the offering (fig. 4). CMOs with the "preferred supplier" status typically have gained this status because of a track record of successfully completed projects. Price plays an important role in the valuation of the offering for commercial supplies, yet less so for quotations involving smaller supplies from pilot plants. Figure 4 illustrates the probability of securing a specific order as a function of the relationship with the customer and the attractiveness of the offering. Offers from newcomers will be considered only for smaller, early stage projects, or if they have a unique technology indispensable for manufacturing a particular molecule.

Conclusions And Way Forward

Identifying, realizing and maximizing business opportunities from new drug candidates are a question of survival for the fine chemical industry. In order for CMOs to successfully manage their business risks and realize the growth strategy through the necessary rejuvenation of their aging product portfolios, a commitment and involvement of the company as a whole is mandatory:

- Management has to define a strategy focused around the pharma and good manufacturing practice (GMP) requirements.
- Business development has to aggressively identify new opportunities, conduct thorough evaluations of the drug R&D pipeline.
- R&D has to be ready to develop lab processes and assist with product technology transfers to the pilot plant while manufacturing and QA have to also participate in delivering demonstration batches and ultimately establishing industrial-scale production.

More than ever, success in pharma fine chemicals will require focus on servicing an industry that is highly regulated but nonetheless growing and with a stabilizing business outlook.

A full version of this article is co-published by Contract Pharma.

Figure 3: Project Initiation Gateways along the Drug Life Cycle
Source: The Division of Science Resources (SRS) of the National Science Foundation; U.S. Institute of Applied Manpower Research, India (2011) 8. World Intellectual Property Report

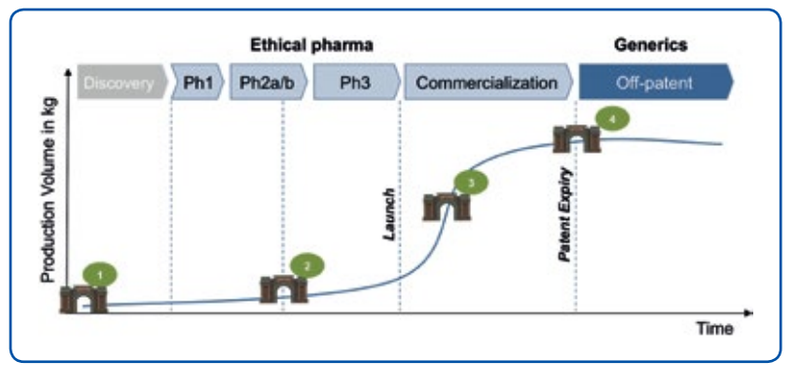
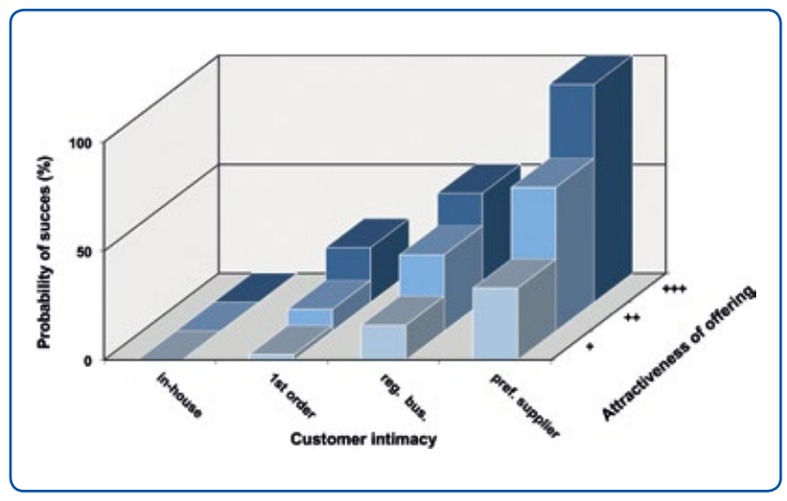


Figure 4: Probability of Securing the Business



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Aesica Unveils New High Capacity Manufacturing Facility

LOCATIONS British Formulator Says £30 Million Investment Reflects Global Demand

Aesica has announced the creation of a new high capacity manufacturing facility following a £30 million investment at its Queenborough, Kent site.

U.K. — The 10,000 m²expansion has been constructed for the production of a solid dose medication used in treating type two diabetes. The company said commercial production at the facility will begin in November. The facility contains a large amount of highly technical and specialist equipment including spray granulators, coaters, tablet presses, a delumper, blender and a sieve system. The design of the facility will allow the current capacity to be more than doubled in the future which would require a further additional 50 staff to be recruited. ■

The Limits of the Biosimilars Revolution

Pharma Management Radar by Camelot Management Consultants

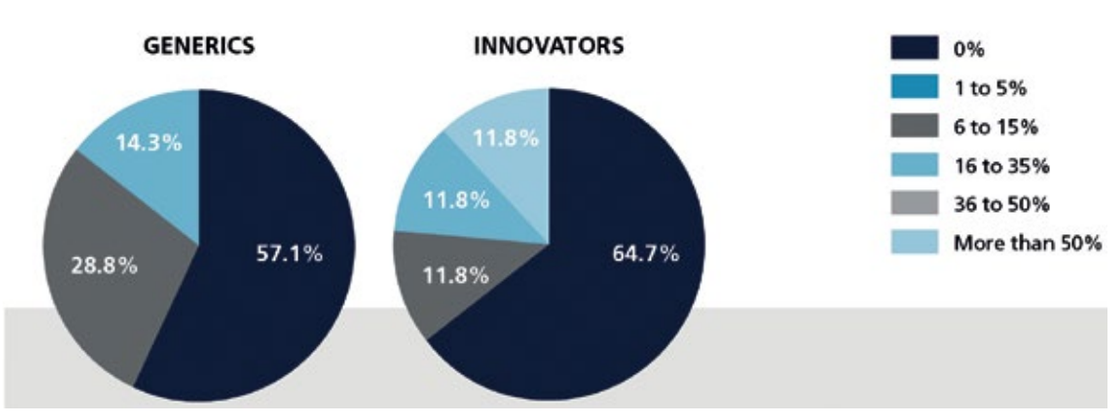
Limitations – The global pharma industry is steering toward the patent cliff; Nine of the 10 top-selling biologicals will lose patent protection by 2020 either in Europe or the U.S.

Michael Jarosch
partner and head of industry segment Pharmaceuticals & Life Sciences, Camelot Management Consultants

Dr. Axel Sinner
principal and head of Camelot's Competence Center Pharma Commercial

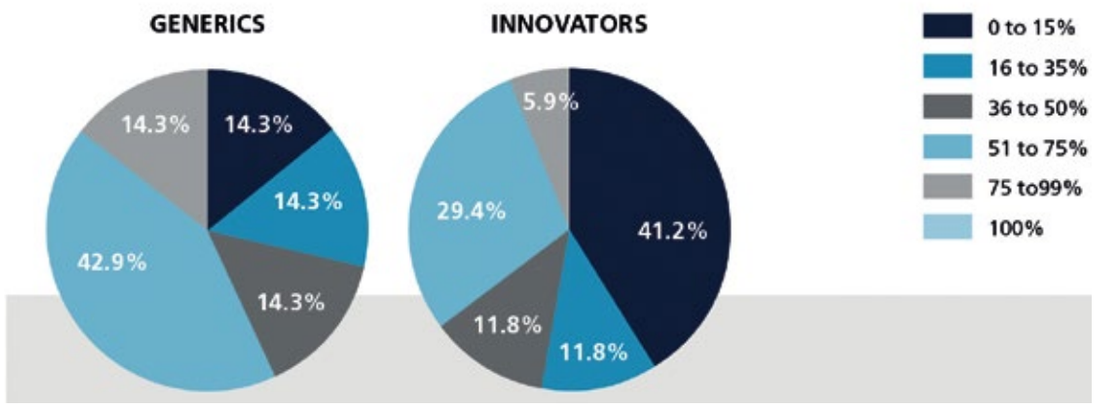
Question:
Assumed impact of Biosimilars

Which proportion of your company's entire product portfolio will be affected by the upcoming Biosimilar market situation in terms of price pressure?



Question:
Development of price levels of Biosimilars

Where do you expect the price level of Biosimilars two years after launch according to the originator price before patent expiry (100%)?



For the comparably new segment of biosimilars, this means a potential market volume of more than $62 billion. Nevertheless, the market actors do not expect the upswing of biosimilars to fundamentally change the entire pharmaceutical industry. This is mainly due to the fact that biosimilars are not expected to be priced as high as the patent-protected originals. Also, the necessary R&D pose a difficult hurdle for many companies.

This is the picture that emerges from the second Camelot Management Consultants Pharma Management Radar survey, a biannual survey that serves to examine the general climate in the pharmaceutical industry. In August and September 2013, the Pharma Management Radar expert panel, consisting of more than 80 executives from globally active pharmaceutical companies based in 16 countries, was interviewed to analyze the influence of biosimilars.

Biosimilars' Limited Effect

Although biosimilars are considered one of the most important industry trends, large parts of the industry do not feel affected. Biologicals play no big role for nearly three-fourths of generics and even half of the innovators. The figures are quite similar when it comes to the future development of biosimilars within the companies' product portfolios. This reflects the mature phase of the decision-making process: Generics that are engaged in the biologicals/biosimilars business today will tend to keep up or even increase these activities. Innovators that are not yet in the biologicals business will most probably not enter the biosimilars market, either.

> *As long as the regulatory environment doesn't change dramatically, biosimilars will not completely change the world.*
>
> Holger Kliebe, Head of Corporate Commercial Controlling, Grunenthal Group

At the same time, some biologicals producers will stay away from biosimilars completely. The reason for this may be that some of the big biologicals innovators avoid biosimilars for image reasons — or just prefer to fully concentrate strategically on patent-protected drugs. Generics and innovators agree that biosimilars will have neither dramatic effects on shifts in therapeutic treatments nor on their respective product portfolios. When asked about the biggest limits that might affect the success of biosimilars, both generics and innovators name "high R&D and regulatory approval cost" as the top problem.

> *While the pharmaceutical industry is still suffering from the Eurozone crisis, some of the established markets seem to be coming back: Demand expectations for North America and Japan are showing considerable growth.*
>
> Michael Jarosch

> *It remains interesting to see how prescribers will handle the substitution of originator biologicals and how payer organizations will play the price game in the competitive area between these biologicals and biosimilars.*
>
> Dr. Axel Sinner

While more than half of the generics executives still expect quite high biosimilars prices at levels around 70%, the innovators' estimations are more pessimistic: More than 40% expect biosimilars prices to drop to only 15% of the prices of the originator or less. All in all the market seems to be divided as far as the expectation of the influence of biosimilars is concerned. More than half of the companies don't feel affected at all; also, half of the panel members expect biosimilar prices to decline rapidly after launch. These two developments will considerably limit the value of the multibillion-dollar market of biologicals coming off-patent in the near future.

See also page 24.

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bit.ly/Biosimilars1

Highly Potent Powerhouse

The Demand for HPAPIs is on the Rise

Small But Mighty – Highly potent active ingredients (HPAPIs) are remarkably effective at small doses. Therapies including oncology, hormones, narcotics, musculoskeletal treatments and retinoids all utilize these compounds. By 2018, the market for HPAPIs is expected to reach over $17 billion, and although the majority of high potency products are manufactured in Western countries many companies around the world is investing in highly sophisticated facilities in order to participate in this lucrative field.

A compound's occupational exposure limit (OEL) is often established using toxicology information from scientific literature in additional to toxicology studies. APIs with an OEL of 10µg/m³ or less are considered highly potent compounds. The exposure limit of a known compound can be determined based on the lowest therapeutic dose, other factors that have to be considered include whether the API is in liquid or powder form, the process of formulation, as well as the frequency of contact. Often, new developmental products may not have toxicity information available. Currently there is no official guidance for the safe handling of highly potent compounds; therefore companies create their own categorization. Since containment varies depending on the toxicity of the product, the handling requirements will also differ greatly. Numerous companies utilize SafeBridge Consultants and their classification system, while many have developed their own, based on their equipment and facilities.

Table 1: Occupational Exposure Limits

API	OEL
ethinyl estradiol	35ng/m³
fentanyl	0.7µg/m³
isotretinoin	5µg/m³
leuprolide	0.02µg/m³
naproxen	5 mg/m³
nicardipine	400µg/m³
paclitaxel	0.8-1.0µg/m³

Investment Into HPAPIs

Many companies have been making strategic deals and investments into high potency manufacturing since it requires people with specific expertise in addition to highly specialized equipment. A lot of high potency manufacturing is kept in house, but over the past few years there has been significant outsourcing of HPAPI manufacturing from big pharma to contract manufacturing organizations (CMO). Often it can be more economically practical to outsource as resource demands and the level of specialization needed increases for small volumes HPAPI. There are also significant challenges with manufacturing HPAPIs. The facilities require high containment technologies, and there is significant cost in specialized equipment. For companies getting involved, the barriers to entry include a lack of guidance in design, limited skills outside of big pharma, and high operating costs.

The acquisition of Carbogen-Amcis supported Dishman's construction of a commercial HPAPI manufacturing site in India. Sigma-Aldrich Fine Chemicals and Fresenius Kabi have each made significant investments into their facilities for handling HPAPIs. Aesica opened a high potency granulation facility in 2012 and announced plans to invest in HPAPI manufacturing as well. Novasep invested €3 million in their HPAPI production capabilities at their facility in France; while Evonik has invested in both their high potency laboratory space and kilogram facility and Lonza has plans to double the existing capacity handling HPAPIs as well.

Highly potent active ingredients (HPAPIs) are remarkably effective at small doses.

Prospects for the Market

Analysts estimate that 25% of the drugs in development globally are highly potent. As medicine becomes more specialized, the number of highly potent drugs being developed will likely increase. It is also expected that competition will drive new technological developments and more high potency manufacturing will be developed in high growth regions of Asia, such as India and China. There are numerous HPAPIs that are losing patent protection in the next few years as well, which will likely drive more generic companies' investment into high potency manufacturing or partnerships to develop these products.

As more drugs are created with higher pharmacological activities, the market will continue growing. More companies will decide the initial investment to develop their capabilities will be worth it, as the market for high potency products grows. While some advancements in manufacturing technology, such as single-use production, could see additional HPAPI manufacturing being kept in-house. The lack of a universal regulatory framework for handling HPAPIs will continue to be a challenge. Those companies with extensive knowledge in the field will continue to dominate the high potency manufacturing space, and the continued demand for such products will compel more companies into this highly technical arena.

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bit.ly/CMI_HPAPIS

Table 2: Examples of Banding Systems & Categorization of APIs

OEL (mg,µg,ng/m³)	SafeBridge Consultants	Merck & Co.	Lonza Group Ltd.
10mg	Category 1: Low Toxicity	Category 1	Category 1
1mg		Category 2	Category 2
100µg	Category 2: Intermediate Toxicity	Category 3	Category 3
10µg			Category 4
1µg	Category 3: Potent	Category 3+	
100ng		Category 4 & 5	Category 5
10ng	Category 4: Highly Potent		
≤1ng			Category 6

Do Your Homework

Sourcing Intelligently From India

'Pharmacy To The World' – In today's global pharmaceutical industry 2.0, emerging regions led by India (BRIC — Brazil, Russia, India, China) have moved to the front row in terms of new market growth, outsourcing production-scale commercial manufacturing, and— most commonly — the sourcing of intermediates and APIs for finished formulations.

India and China these days command more and more attention for sourcing pharmaceutical ingredients and finished generic drugs. China and India now source 80% of active pharmaceutical ingredients (APIs), and India provides the U.S. with 25% of its generic drugs while at the same time India is heavily expanding its "pharmacy to the world" reach.

Experiences or results when Western companies source from India vary widely, from successful to "could have been better" to "what a nightmare!"

Why is that? In a nutshell: homework (or lack thereof).

To start with, India is a land of contrasts and presents challenges with its myriad languages, customs, religion and culture.

Where else in the world can anyone find:

- Electronic voting machines being transported on elephant backs?
- Fiber-optic cables laid by digging out concrete or dirt roads with picks and shovels?
- Yet find:
- A global state-of-the-art cytotoxic, Category IV HPAPI (high-potency API) manufacturing facility that matches, even exceeds, European and U.S. occupational exposure limits (OELs) and containment standards but can perform and deliver at a substantially lower cost.
- The largest number of manufacturing facilities approved by the U.S. Food and Drug Administration outside the U.S. (close to 200), many with their own U.S. FDA generic abbreviated new drug applications filed.
- A unique dhaba walla system that delivers thousands of homemade, precooked lunches in stacked aluminum containers all over Mumbai offices on foot, bicycles and trains without computerization by mostly illiterate couriers that has earned a Six Sigma standard of reliability or accuracy rating from Forbes magazine.

To source from India successfully, one needs to understand India first, i.e., the history and evolution of the pharmaceutical industry, its entrepreneurial and highly fragmented state, and its people and culture. Buyers can then better map their needs against the supply chain and navigate the sourcing terrain while avoiding "land mines."

Let's Get Started

India today is arguably considered the 800-pound gorilla of generic drugs. The Indian pharmaceutical industry is the third-largest in the world in terms of volume but stands only 14th in rank by dollar value.

India, however, provides 25% of the generics in the U.S. markets. Since 80% of drugs consumed in the U.S. are generics, this essentially translates to India supplying 20% of the drugs in American medicine cabinets. Indian pharma manufacturing is cheaper and for the most part meets good manufacturing practice (GMP) quality mandates demanded by the U.S. Coupled with the global appetite for generics these days, this explains India's rise.

Memory Lane

How did India pharma get here? What was the Indian pharmaceutical industry like before it evolved?

Soon after India's independence in 1947, India's pharma industry was largely dominated by Western multinational corporations (MNCs), with eight out of 10 of the largest firms being foreign.

The Indian pharmaceutical industry was largely import-dependent through the 1960s until the Indian government initiated policies stressing pharmaceutical production in India. Then along came the New Patent Law in 1970, which basically mandated that patents would be granted only on the process level not the product level.

MNCs soon found extreme competition from government and private sector reverse engineering drug molecules by altering some of the manufacturing process, bypassing patents to get approval for markets in India. This drove MNCs out of the Indian pharmaceutical markets, at least for while.

This led to the rise of thousands of entrepreneurial and in some cases government-led enterprises.

In 1984, the Drug Price Competition and Patent Term Restoration Act, informally known as the Hatch-Waxman Act, was passed in the U.S. That spawned and legitimized the generics industry globally, starting with the U.S. But by then, India had developed a cadre of scientists, engineers, entrepreneurs and investors that recognized a generics bonanza was ahead with the passage of the Hutch-Waxman Act in the U.S.

Finally, the Patent Act of 2005 came along, and Trade-Related Aspects of Intellectual Property Rights (TRIPS) mandates obliterated the Indian pharma process patent "free ride." India buckled to the WTO, and now Indian manufacturers were forced to comply with product patents. But Hutch-Waxman provided the Indian pharmaceutical industry with an alternative route that leveraged India's copycat prowess.

With India's past astute legislative reforms (process vs. product patent), the growth in pharmaceutical contract manufacturing and outsourcing plus India's mastery of reverse molecule re-engineering peppered MNCs and more novel technology, India has labeled itself as the "pharmacy to the world."

India's culture and languages are as diverse as its spices; expert Ram Balani recommends anyone interested in sourcing from there to get to know the country first hand.

Fast-forward to today: India has close to 20,000 pharmaceutical firms, most of which are small companies. A survey by the Federation of Indian Chambers of Commerce and Industry (FICCI) tells the story, that is, the fragmented pharmaceutical scenario in India with 5,700 small firms vs. only 100 large companies.

So why does this matter? India has a highly fragmented pharmaceutical industry, which one needs to keep in mind when sourcing APIs or finished formulations or even outsourcing manufacturing, custom synthesis or R&D in India.

Calibrating your approach is key to dealing with India; there's no "one size fits all."

Know Your Supplier

You have to know whom you are dealing with in India, then map your business practices accordingly.

Dealing with a small to medium-sized manufacturer of API, for example, demands you force Western discipline into what seems like a disorganized, mostly verbal and undocumented, make-it-up-as-you-go-along mentality from your Indian supplier. Social "bonding" needs to be a prelude to talking business. You will likely be dealing with younger second-generation family members handed down a family business they run with advice from a senior, more experienced, professional the founder hired but who is powerless to make decisions.

On the other hand, though large enterprises conduct business in a manner more familiar to Westerners, they are not immune to India's grip on culture and religion. Delivery deadlines could be missed because the senior employee-in-charge, for example, had to travel to his hometown for a sudden wedding or known religious holiday left out during project planning and scheduling discussions.

Then there's the Indian "wobble," unique to India.

An Indian nodding his head side to side often means an agreement to the context of the conversation but could also be a polite way to acknowledge what is being said with hesitation to say "no." Old India traditions are steep; Indians find it hard to say "no," so best you ask with a question like, "Do you agree?" and wait for an answer.

Get to know India first with your feet on the ground if possible. Leave those expensive market analysis reports back home.

Ram Balani, CEO and founder, FDA Smart

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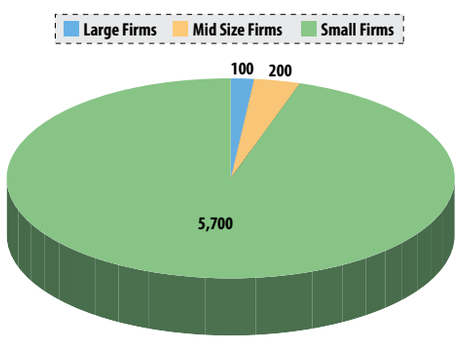
bit.ly/CMI-India

India's Pharmaceutical Firms by size



Source: Ram Balani © CHEManager Europe

Novartis Looks at Underperforming Business Units

PORTFOLIO Speculation Abounds that Swiss Drug Maker Might Sell Units

Novartis may take a leaf out of its past deal-book as the Swiss drugmaker conducts a review into some of its underperforming businesses, a board member said.

Switzerland — New chairman Joerg Reinhardt has launched a review of the drugmaker's portfolio fanning speculation that some of the company's smaller units could be sold, spun-off or integrated into other divisions.

Novartis board member Pierre Landolt cited agrochemicals company Syngenta — formed in 2000 through the merger of Novartis' Agribusiness and Zeneca Agrochemicals — as a guide for how the drugmaker could unlock value for shareholders.

„There are markets in which we have to grow. Syngenta could be a model there," Landolt, who is also chairman of the Sandoz Family Foundation that owns 3.3% of Novartis's share capital, said in an interview for the Basler Zeitung newspaper.

„Back then we succeeded in creating a new type of integrated agro-group through a combination of spin-off and fusion. Perhaps there are other activities in the company which could be developed in this way," he said in the paper's weekend edition.

Syngenta is now the world's No. 1 maker of crop chemicals with a market value of $38 billion.

Reinhardt, who took over as chairman on Aug. 1, has defended Novartis' diversification strategy, but stressed the company would only hang on to companies that are among world leaders. He has also said a $10 billion buy would not be out of reach.

Global drugmakers have stepped up the pace of restructurings, as investors clamor for management to unlock value trapped inside large firms.

If Novartis were to consider spinning off its animal health unit, it would be following in the footsteps of Pfizer that spun out its operations in this area into a new company called Zoetis last February.

A Safe and Secure Pharma Supply Chain

Preventing Counterfeits Using Track and Trace Methods

Safety Net – With the increasing threat of counterfeit medicines entering the legitimate supply chain, there is a need to introduce a standardized identification system to accurately establish the identity of each individual pharmaceutical product. In order to tackle the escalating issue of counterfeit and falsified medicines, a unified approach is required.

Ian Parsonage
Director of Global Serialization Services, PCI

Recent regulatory requirements introduced in the European Union have stipulated increasingly stringent measures for pharmaceutical companies to implement track and trace technology. This technology is a serialisation method that can improve traceability and transparency within the supply chain, providing increased confidence that only legitimate products are being taken to market. The pharmaceutical industry has a significant role to play in implementing the right technology into their processes, so that medicines can be accurately identified and tracked throughout the supply chain.

A United Front

Dispensing and dosing errors, reimbursement issues and cases of counterfeits in the legitimate pharmaceutical supply chain have highlighted the need to establish more clearly and effectively the identity of each individual medicine pack. The European supply chain is becoming increasingly complex, with billions of pharmaceutical products being transported and sold across the EU each year in an increasingly fragmented supply chain. This has resulted in a lack of transparency and increased difficulties in providing a full genealogy of medicines in the market place.

To tackle this issue effectively, there needs to be a united effort from the pharmaceutical industry, regulatory bodies, wholesalers and retailers to establish a standardized identification solution. A database where uniquely identifying bar codes on drug packaging can be verified at point of dispensing would significantly improve the ability to track pharmaceutical products on a global basis; there is an urgent need to improve traceability within the supply chain. Serialization technology provides the ideal solution to enhancing efficiency in the supply chain, reducing theft, counterfeit products and allowing manufacturers, distributors, retailers, pharmacies and end-users to ensure compliance with industry regulations.

Drive to Establish Regulatory Compliance

In order to sufficiently protect public health interests and the relationship of trust between patients and pharmaceutical suppliers, the entire production and supply chain needs to be closely regulated. The pharmaceutical industry operates on a global scale, and regulatory compliance across multiple geographies is fundamental to ensuring that the supply chain remains safe and secure.

The lack of a standardized system or recognized industry standard for the identification and coding of pharmaceutical products within Europe has resulted in many EU countries proposing and developing their own individual coding systems. These systems all differ in terms of the content of each code, through to its physical placement. The lack of a coherent approach to verifying scanned bar codes on drug packaging has undoubtedly contributed to the growing problem of pharmaceutical counterfeiting.

To combat these issues, the EU is pursuing the implementation of a standardized coding system that will include unique identifiers on each individual pack of medicines throughout EU member states. Following the successful trial of a point of dispensing verification system in Sweden in 2009 and 2010, the Falsified Medicines Directive (FMD) was published in July 2011, requiring the introduction of serialization and anti-counterfeiting measures throughout the pharmaceutical supply chain. EU member states were required to adopt the measures by January 2013, and pharmaceutical companies must be fully compliant with the requirements by 2017 in order to be eligible to trade within the EU.

In 2011, the European Federation of Pharmaceutical Industries and Associations (EFPIA) created the European Stakeholder Model (ESM), with the aim of establishing a system for verifying pharmaceutical products in compliance with the FMD. Key stakeholders in the pharmaceutical industry, including manufacturers, distributors, wholesalers and pharmacists are now working in partnership under ESM to implement a standardized identification solution for pharmaceutical products across Europe.

The solution developed by ESM partners is the European Medicines Verification System (EMVS), a cost-effective dispense coding and serialization system which uses 2D barcoding to verify the authenticity of medicinal products. The codes are generated and applied by manufacturers using a 2D data matrix barcode containing a unique serial number. Pharmacists can then check the identification code on each pack at point of dispense. This solution meets the requirements for pack identification under the FMD and will go a long way to combat the entry of falsified medicines in the EU supply chain ensuring patient safety across Europe.

Challenges Facing the Pharmaceutical Industry

The regulatory changes taking place will have a significant impact at the manufacturing and quality control level, and businesses will need to ensure they are compliant with standards throughout all their processes.

Counterfeit drugs are estimated to cost 7-10% of global pharmaceutical market revenue; there is a strong desire within the industry to implement track and trace technology to help overcome this issue. As well as being potentially life threatening to the patient, counterfeit medicines can damage a business' reputation, and many pharmaceutical companies cannot match the low cost competition, resulting in a loss of revenue, which would otherwise provide funding for further research and development. In addition, pharmaceutical companies must now also find cost effective ways of complying with legislative requirements.

As is often the case with the implementation of many new technologies and techniques, there are concerns over the associated capital expenditure and installation of additional equipment throughout the supply chain and in particular, at the point of dispensation. In order for the system to be successful, it will be essential to establish who will be responsible for covering the cost of the new barcode readers for the end-supplier. If smaller independent retailers are unable to afford to put the necessary measures in place, the system will not be effective. There are also concerns over the potential disruption to existing production processes, as any time delays in production can result in pharmaceutical companies incurring significant costs.

The Track and Trace Solution

With industry guidelines stipulating the need for more stringent measures to combat falsified and counterfeit drugs, pharmaceutical companies are increasingly introducing track and trace technology into their production processes.

Track and trace is a serialization method that can help to protect against counterfeiting and the falsification of medicines by authenticating, monitoring and controlling the flow of medicines throughout the supply chain. Serial numbers can be traced at various points throughout the supply chain which makes it easier to identify where counterfeit products have entered the chain and also allows for full traceability.

Ultimately, the primary aim of the technology is to protect the pharmaceutical supply chain and guarantee patient safety. However, there are a considerable number of business and economic benefits that can be gained from the practice helping to overcome a number of challenges faced by pharmaceutical companies. Due to the risk counterfeit pharmaceutical products pose to patients, they can tarnish the reputation of a brand, leading to reduced revenue and market share. Serialization techniques make it easier to identify counterfeits and help protect genuine pharmaceutical brands. In line with this, secure and traceable products are much more appealing to customers which can help to create a competitive advantage.

Delivering a Secure Supply Chain

In response to the challenges facing the pharmaceutical industry, companies such as Packaging Coordinators Inc. (PCI) are working to provide secure packaging solutions to support their customers in fully complying with new international standards to secure the supply chain against counterfeiters.

A key priority for pharmaceutical companies is having absolute confidence that only safe products that are compliant with domestic and international packaging requirements are taken to market. Sophisticated security systems can be put in place to monitor product flow throughout the packaging process, from the receipt of incoming bulk product to storage, transfer, processing, and final shipment.

The PCI serialization system is an end-to-end, point-of-dispense identification solution which uses a unique identification code on each pack, generated and applied by the packer. The system uses data structures defined by GS1 in their Global Traceability Standard for Healthcare document to create a "license plate" or serial on each pack. This number, when combined with the Global Trade Item Number (GTIN) creates a globally unique number. Each license plate also contains a 2D data matrix code together with the human readable data contained within, for example; serial number, GTIN, lot number and expiry date. Each pack can then be associated with its bundle and further with the shipping container and finally with the pallet with all of this aggregation information being stored and moved around the supply chain.

The product verification process then compares the data held within the data matrix code, with a secure product record on a database shared between the supplier and the customer. This provides confirmation that the product record exists and matches the data held on the product itself, as well as checking that it has not been previously marked as "dispensed" or that it does not contain any warning or advisory notes. This verification process would immediately alert the pharmacist if a packet containing the same number had been released into the supply chain.

Track and trace solutions need to accommodate different manufacturing sites and technologies, regulatory regimes and product requirements. Flexible and customizable track and trace solutions can be provided to meet a client's specific needs and can be easily integrated to ensure minimum disruption to existing manufacturing lines.

PCI has chosen the track and race solution from Antares Vision to manage the delivery of serialization at both line and site levels on a global basis. This system merges information received from PCI's customers with data held within its own ERP system to deliver the serialization to the customer's product. Serial activation and aggregation data can then be sent securely in B2B transactions to enable a customer's system to prepare for the receipt of serialized product and then perform its onward distribution.

Conclusion

The threat of counterfeit and falsified medicines is a global issue and therefore requires a united global approach to tackle it effectively. The serialization of pharmaceutical products and the ability to effectively track them is essential to the creation of a truly safe and secure supply chain. The formation of a unified, single-source, pan-European or even global database where scanned bar codes can be verified at the point of dispense is the crucial next step in the creation of true serialization and supply chain security.

The introduction of regulations requiring the implementation of a standardized track and trace system, combined with the commitment of pharmaceutical companies throughout Europe, as well as globally to the use of this technology will go a long way in creating a safe, secure and trustworthy supply chain. That is not to say that achieving a harmonized identification solution on a global scale will not represent a significant challenge, but once it has been effectively established, the benefits will be hugely significant. It is imperative that the pharmaceutical companies act now to overcome one of the most significant challenges facing the industry.

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bit.ly/CMI_Track-Trace

GlaxoSmithKline India Hit By Drop In Bulk Orders GlaxoSmithKline's Indian business has been hit by a drop in sales which two industry sources said was linked to a protest by bulk buyers against a cut in their profit margins under a new government drug pricing policy. GlaxoSmithKline Pharmaceuticals said bulk sellers in "major pockets" of India had stopped buying the company's drugs since Sept. 15.
The two sources said wholesalers and retailers in many parts of India had stopped buying medicines from some companies in protest against a reduction in their profit margins under a new government pricing policy. Under the recent policy change, the prices of 348 drugs deemed essential are now being regulated, compared with 74 previously. The move has curbed prices of costly brands sold by drug makers in a market that already has rock-bottom medicine prices.

AstraZeneca CEO Gets Two Cheers after First Year in Job Fixing AstraZeneca remains a work in progress for Chief Executive Pascal Soriot, with sales and profits still heading firmly downhill after his first year in the job. Yet confidence is slowly building that he may have the right long-term prescription for the British group; Soriot has shunned a big acquisition as a way to plug the deep revenue gap left by multiple patent expiries, opting instead for a string of smaller deals, a reboot of the drug pipeline and a shake-out of top management.
His approach has resonated with many younger researchers who felt the group was drifting, following past R&D setbacks. It has already accelerated work on several promising cancer drugs.
Rival executives say he is borrowing some ideas from Switzerland's Roche. Roche — particularly its Genentech biotech unit, which Soriot used to head — is renowned for its R&D successes, something Soriot hopes to replicate with a $500 million move of AstraZeneca operations to Cambridge, a British science hub.

Carbogen Amcis Makes Capital Investments in ADC Capabilities Switzerland-based Carbogen Amcis announced a series of significant investments aimed at enhancing its antibody drug conjugate (ADC) capabilities to better respond to increasing demand for ADCs in the development of highly targeted cancer treatments. The investments include a $4 million clean room clinical supply facility at the Bubendorf, Switzerland, site and a $950,000 upgrade of the sterile manufacturing area at the facility in Riom, France. By adding on to the current high potency facility, Carbogen Amcis said it is positioned to offer its partners seamless development and manufacturing services for ADCs.

Merck & Co. to Slash Annual Costs by $2.5 Billion, Cut 8,500 Jobs Merck & Co, taking a cue from rival drug makers that have slashed research spending to bolster earnings, said it will cut annual operating costs by $2.5 billion and eliminate 8,500 jobs, or more than 10 % of its global workforce. The U.S.-based company said it aims to narrow its focus to products with the best chance of winning regulatory approval and achieving substantial sales. The job cuts would be in addition to expected remaining cuts of 7,500 positions from a 2011 restructuring that involved elimination of 13,000 positions.

Materials Enable Sustainability Improvements

Material Innovations Steer the Drive for More Sustainable Products

Corporations Get a Push from Plastics – For global material companies such as Styron, R&D departments have become increasingly important to enhance our customers' sustainability efforts. In every region and every market, sustainability is high on the agenda, primarily because of increased regulation but also to a large extent because of increased customer awareness and demands.

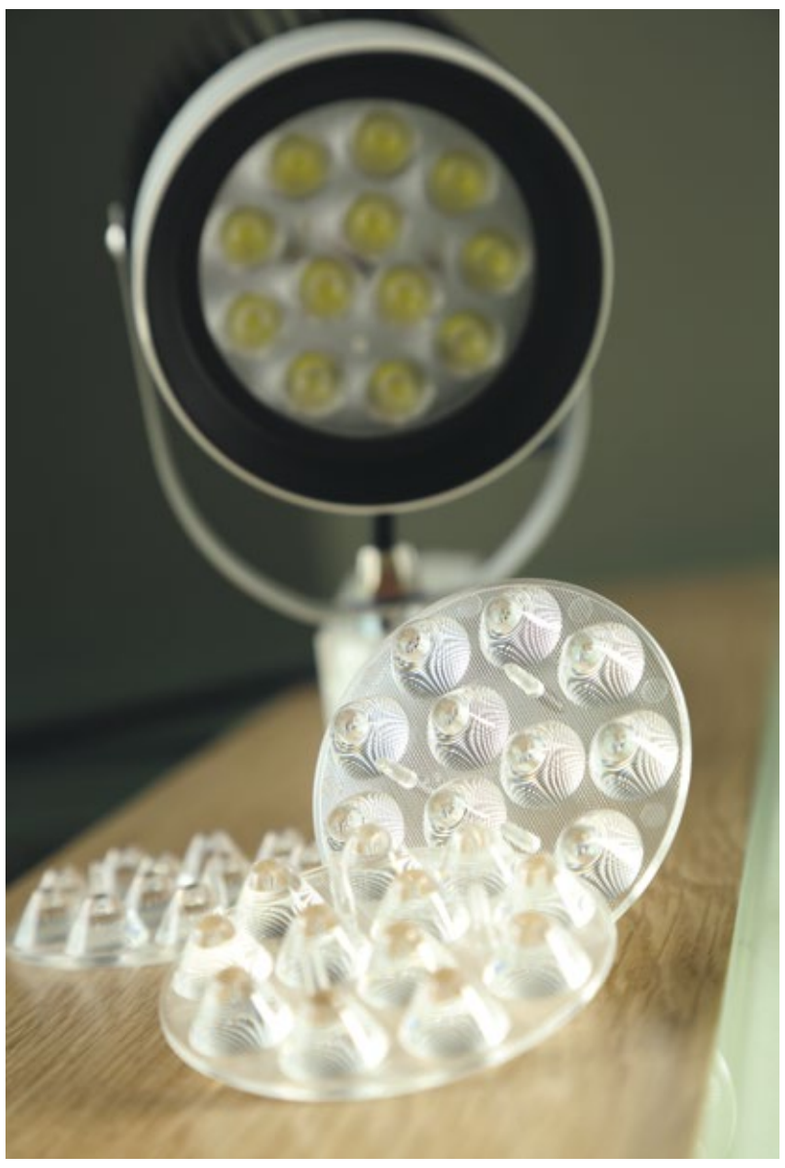

Fig. 1: Polycarbonate resins are an important component in LED lighting

Consequently, plastics innovations have become critical to the overall performance of end-applications in several markets and are intrinsically linked to the sustainability strategies of corporations. With a strong commitment to sustainability, Styron continues to push the technology boundaries in markets such as electrical and lighting, automotive and tires by addressing considerations such as down-gauging, flame retardancy and low rolling-resistance. Styron's global R&D team is continuously on the lookout for high performance products and engineering processes that help to ensure safe, long-lasting operation of sustainable applications every step of the way.

Making A Right Turn Towards Improved Energy Efficiency

The electric vehicle (EV) market is gaining momentum with traditional automakers recognizing the need to move into this direction. Especially in electrical cars, lightweight is an area to address. Prior to the launch of some of the new electrical car models, Styron Automotive has been collaborating closely with several of the key electrical car producers to considerably decrease the weight of interior components.

Fig. 3: green tires will significantly contribute to improving fuel efficiency and reducing CO_2 emissions

Also, for EVs to gain widespread consumer adoption, an infrastructure of charging units outside and inside the home is critical. Electrical vehicle charging units are a growing application for Styron, with special demands on the polymer performance, particularly in terms of design freedom, impact at a range of temperatures, extreme mechanical loads and resisting vandalism, while providing ignition resistance. Styron has been closely collaborating with the utility market, especially in Southern Europe, to develop the next generation of charging stations made with polycarbonate (PC)/Acronitrile-butadiene-styrene (ABS) blends. Due to its mechanical and physical properties, PC/ABS is an appealing choice of material. The chargers' casings can withstand heat, aging and humidity, while their internal electrical connections exhibit enhanced functional longevity compared to traditional materials such as steel.

Styron's next generation of charging stations are being developed with advanced resins that address all performance requirements, in combination with an effective chlorine- and bromine-free flame retardant package to support sustainability requirements.

Illuminating the Road to Improved Light Efficiency

When it comes to lighting efficiency, LED (solid-state) lighting is playing and will continue to play an increasing role in the marketplace. Energy Star estimates that residential LED lighting uses at least 75% less energy and lasts at least 15 times longer than incandescent lighting. Polycarbonate resins are an important component in LED lighting, and have proved to be a more sustainable option, not only because of durability, but also because they offer high transparency for LED display lighting and can be suitably modified for exceptional opalescence when required for light diffusion.

All these elements make material development integral to the performance of more sustainable lighting. Styron's R&D team is working on several development projects with lighting industry, particularly in China, to further enhance high transmission light in LED lighting. Recently, Styron has developed a proprietary opalescent technology that ensures optimum light management by giving the plastic part a special luminous performance (e.g., the invisibility of the light source behind the diffuser or the globe). In addition, we are continuing the application of flame retardant technology, which supports the drive toward very low wall thickness, while maintaining high transparency and product safety.

Fig. 2 : First-in-Market Thermoplastic Lift-Gate Solution for the New Renault Clio. Styron contributed in the engineering phase, but also brought in its expertise in the material development implementation phase to select and test the materials required to fulfill the specific requirements

Marking the Road to Improved Fuel Economy

Improving fuel economy is a top priority in the automotive industry. Leading car producers are making significant changes in material selection and also in the engineering methodology behind vehicle design. Due to the inherent relationship between vehicle mass and fuel consumption, light-weighting of cars is key to meeting efficiency requirements. A polymer solution that is continuously finding inroads for light-weighting is long-glass-fiber-filled polypropylene (LGF-PP). LGF-PP provides automotive components with strength and impact resistance, thereby enabling lighter parts and allowing for thin-walling of structural applications. Styron is addressing this trend by assisting automotive original equipment manufacturers (OEMs) and their tiers across the globe in replacing steel components with long-glass-fiber-filled composites as well as in application engineering.

The Renault Clio is a prime example. The concept was jointly developed by Renault and Styron's R&D departments. Through a successful synergy, the French carmaker not only achieved weight reduction of 10% for optimal fuel efficiency but also responded to their waste management guidelines promoting recyclability without disassembly by creating this mono-material solution. With the knowledge that the base polymer of the lift-gate solution was the same material, the part can be easily recycled.

Styron played an important role from development to manufacturing of the product. The Styron and Renault teams collaborated closely in the engineering phase to design the optimal structural part for the lift-gate. Styron also used its material characterization expertise to select and test the materials required to fulfill the specific requirements for a lift-gate and to predict lift-gate performance characteristics via computer-aided engineering (CAE) simulations. To help improve impact resistance, expansion and durability of the structural part of the lift-gate, Styron's engineers introduced a long-glass-fiber polymer.

Navigating the Path to Reduced CO_2 Emissions

Advancements in low rolling-resistance tires, also known as "green tires," will significantly contribute to improving fuel efficiency and reducing CO_2 emissions, especially in light of the fact that tires account for 20% to 30% of total fuel consumption, according to the Official Journal of the European Union.

Styron has used its strong understanding of solution styrene butadiene rubber (S-SBR) to develop the latest generation of functionalized S-SBR. This technology, in combination with the tire design improvements, has enabled Styron to improve its offering to customers. Tire makers are able to build efficient tires with a lower rolling-resistance without compromising on grip performance. Styron is continuously committed to introducing more innovative products to meet the high standards set by the recent EU tire-labeling regulation. Our ultimate goal is to support global mobility, while reducing the carbon footprint and creating a more sustainable environment.

With the introduction of Styron's enhanced S-SBRs, we have further demonstrated our commitment to providing sustainable solutions by creating an opportunity to reduce fuel consumption by 4g/km. For Europe, this equates to a reduction of 34 million tons of CO_2. This reduction corresponds to the global forecast for an increase of CO_2 emission levels for transportation in the next two years.

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Quo Vadis Phthalates?

Road Ahead for High Phthalates

This evolution in the science around phthalates and their legal classification has been closely followed by the global market.

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Not All Created Equal – The European plasticizers market has evolved considerably in the last decade, moving away from classified low phthalates to nonclassified high phthalates and alternative plasticizers belonging to different chemical classes. However, some phthalates continue to be in the spotlight of regulators, environmental nongovernmental organizations and consumer groups. The industry continues to work on making sure that consumers, media, industry and policymakers understand the difference between high and low phthalates.

Phthalates are broadly divided into two groups — high and low — according to their molecular weight. They are different in terms of applications types, their health and environmental effect, and their legal classification. In the case of low phthalates (known under acronyms such as DEHP, DBP, DIBP, BBP), they are classified as substances of very high concern (SVHC). Under the REACH regulation, SVHC substances that will not be granted an authorization for specific applications will be subject to specific phase-out dates; for low phthalates this is Feb. 21, 2015.

However, specific concerns related to phthalates continue to be mistakenly extended to the entire family when high phthalates actually can be safely used in all current applications. Extensive risk assessments performed by independent sources and EU authorities have concluded that high molecular weight phthalates (DINP, DIDP, DPHP) pose no risk to human health in current applications. They do not require any classification or labeling nor are they on the REACH Candidate List for Authorization.

Market Trends

This evolution in the science around phthalates and their legal classification has been closely followed by the global market. In the EU in particular, demand has been steadily shifting away from low molecular weight phthalates (LMW), which were in widespread use until the 2000s, toward high molecular weight phthalates (HMW), which today represent around 85% of all phthalates being produced in the EU.

At the global level, the trend is quite different; DEHP still represents around 50% of all phthalates used worldwide. It is also important to note that the non-phthalate plasticizer market segment is growing in Europe and elsewhere in the world.

Policy Update

The REACH regulation has been instrumental in further defining the differences between the two main groups of phthalates. In the case of DEHP, BBP, DBP and DIBP, they must follow the authorization process to determine if they can continue to be used in specific applications beyond their sunset date of Feb. 21, 2015. As of Aug. 21, the phthalates authorization application window has closed, and the European Chemicals Agency (ECHA) has announced that several dossiers have been submitted. ECHA said it would disclose details of these applications when the related public consultations start in mid-November.

Three of these low phthalates (DEHP, DBP and BBP) have also been included on the Restriction of Hazardous Substances (RoHS) Directive list of potential substances to be restricted in electrical and electronic equipment.

The ECHA recently concluded in its re-evaluation of the restrictions on DINP and DIDP in toys and childcare articles that no further risks have been identified from the use of these substances by adults or children. While the existing restrictions are maintained, it can be concluded that DINP and DIDP are safe for use in all current applications. The final decision from the European Commission is expected later this year.

National Initiatives

Pressure at the national level in Europe has been coming mainly from Denmark and France, with Denmark working on its own national phthalate strategy and France working on a national endocrine strategy. In Denmark, a national ban on low phthalates — DEHP, DBP, DIBP and BBP — was announced in December 2012, later to be postponed by two years. This ban will now be effective as of 2015. The main reason for this postponement is that these four low phthalates continue to be used widely outside the EU in the manufacture of electrical and electronic equipment and other articles that are subsequently imported into the EU. Thus retailers in Denmark who are importing these articles asked the Danish government to delay the ban.

In addition to the work on an upcoming national endocrine strategy, France has already passed a ban on DEHP in medical tubing used in pediatrics and maternity wards, effective in July 2015. The debate around these substances, often linked to the issue of endocrine disruptors, has been high on the media and political agendas in France, influenced in part by the strong pressure exerted by NGOs, campaigning scientists and consumer groups.

Public Debate And Misconceptions

In public and media debates, participants often mistakenly use the general term "phthalates" when talking about some of them, thus implying that they all have negative health effects, such as being endocrine disruptors. However, there is ample research on the safety of high molecular weight phthalates, which should not be ignored. In fact, most studies claiming to prove that phthalates are endocrine disruptors have studied only DBP or DEHP, both classified as toxic to reproduction.

It is therefore important to avoid making unjustified, undifferentiated and generic claims when referring to the effects of single substances that are not relevant to the entire family.

Another common misconception is that phthalates can readily "leach out" from articles and migrate into the surrounding environment. However, it is actually quite difficult for phthalates to separate from the plastic in which they are physically bound following high-temperature processing. Reports of these plasticizers causing asthma and allergies have since been shown to be unfounded and scientific studies have concluded that household dust does not correlate to human exposure levels for phthalates, and neither is it an indicator of indoor air quality.

The Future

It has taken more than 20 years and cost billions of euros to develop large enough volumes of high phthalates to satisfy the needs of tens of thousands of companies throughout the supply chain. High phthalate producers, who are strongly committed to product safety and the use of science and risk assessments, have constantly supported their customers to enable this transition. In addition, plasticizer producers are working on improving the sustainable use of additives as part of the work accomplished by VinylPlus, the European PVC industry sustainability program.

Ensuring that the differences between high and low phthalates are effectively communicated and understood remains a key challenge for the plasticizers sector, although progress has been made in recent years. The industry will continue working hard to provide the information needed by policymakers, regulators, users and other stakeholders to help ensure that society has the benefits of flexible PVC articles and that they are safe and environmentally sustainable.

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Drastic Transformation

VinylPlus: Taking the Lead in the Quest for Sustainability

United Industry – Twenty years ago, it was hard to imagine that increasing concerns about the way PVC was produced would trigger such a radical industry transformation. In its third year, VinylPlus is well on target to meet the ambitious, new 10-year goals carrying the work started with Vinyl 2010 to the next level.

Brigitte Dero
general manager, European Council of Vinyl Manufacturers, DGM VinylPlus


© Maksim Samasiuk - Fotolia.com

Everything started 13 years ago with the launch of Vinyl 2010, the first-ever sustainability program of the European PVC industry. Based on the voluntary commitment of the entire value-chain — resin manufacturers, additive producers and converters represented by their respective European associations (ECVM, ECPI, ESPA and EuPC) — all its members renewed their sustainability pledge in June 2011. VinylPlus was born.

Bigger Challenges, Ambitious Goals

While it initially aimed to address the industry's waste management needs, at the completion of Vinyl2010 the targets set had been met and exceeded in many cases. The achievements are particularly notable when it comes to collection and recycling. In 1999, there was no infrastructure for PVC recycling in Europe, and many dismissed it as an unrecyclable material. At the end of the program almost 1 million tons of PVC had been recycled in Europe. Additives such as cadmium stabilizers have been phased out.

Achieving the initial goals gave the PVC industry the necessary confidence to launch VinylPlus, with more ambitious recycling targets, product stewardship guidelines on the sustainable use of additives, investment in R&D initiatives and the promotion of a sustainable development culture. When it comes to waste management, the industry aims to recycle 800,000 tons per year of PVC by 2020 including 100,000 tons of difficult-to-recycle waste.

Recycling, The Program's Cornerstone

When it comes to recycling, one of the main pillars of this program, the numbers speak for themselves. In 2012, VinylPlus registered a record 362,076 tons of PVC recycled. Post-consumer and limited types of post-industrial PVC, including some of the regulated waste streams in the EU, are accounted for based on the new, wider scope of the program. The industry, which has been working for years on technologies to recycle difficult-to-treat PVC waste such as VinyLoop, is currently evaluating a number of innovative processes.

Significant efforts have been made to address the issue of "legacy additives," i.e., the presence of certain substances in recycled PVC that are, or may be, restricted or prohibited in the future following the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation. A solution has been found for cadmium and, very recently, for DEHP. More discussions with the European Commission are, however, necessary to find a way that will reconcile resource efficiency and consumer safety.

The sector also registered a decrease of 76.37% in lead stabilizer consumption in the EU-27 compared with 2007 levels, well on track to complete the substitution by the end of 2015.

Working Harder in Times of Crisis

PVC is one of the most widely used plastics in the world, after polyethylene and polypropylene. However, difficult economic times have taken their toll on the industry. According to recent market figures that IHS Chemicals presented at the 2013 VinylPlus Sustainability Forum, the construction sector's downturn has had a deep negative effect, shrinking margins and putting Europe in a risky position compared with fast-developing economies such as China, India or Turkey.

Speaking at that same event co-organized by ECVM and VinylPlus, the European Union's Director of DG Enterprise Gwenole Cozigou said, "The EU needs a strong industrial base but this has not always been the case. The current economic crisis has been a wake-up call."

He highlighted the need for manufacturing to be "the backbone" of our economy, especially when taking into account that about 80% of research and development comes from this sector.

Competitive And Sustainable

Indeed, the slowdown in Europe has more than ever established the need for a globally competitive and sustainable industrial sector. Both goals are part of VinylPlus' genes as the program strives to increase resource efficiency as a way to create jobs and new opportunities, drive down costs and boost competitiveness while minimizing energy consumption and greenhouse gas emissions.

In that sense, a number of VinylPlus task forces are fully operational, studying how to incorporate renewable energy and raw materials, the sustainable use of additives and the environmental footprint of PVC production. A VinylPlus product label concept for PVC products has been developed in collaboration with the Natural Step — a nongovernmental organization providing input and guidance for the development of the VinylPlus program — and the U.K. expert certification body BRE Global.

Dialogue: The Recipe for Success

A special trait of VinylPlus has been its bottom-up development — an open process of stakeholder dialogue with industry, NGOs, regulators, public representatives and users of PVC — as well as its critical partnership with the international NGO the Natural Step (TNS). The System Conditions for a Sustainable Society developed by TNS were used to define the program's key challenges and objectives, including the need to widely promote sustainable thinking at a global level.

Raising sustainability awareness is indeed a key component of the program, recognizing that progress will be equally dependent on widening understanding throughout industry, as well as in society generally. In that regard, a number of communication projects have been supported to reinforce the Voluntary Commitment messages along the value chain. VinylPlus is also engaged in external debates including the participation at Rio+20, the United Nations Conference on Sustainable Development. The VinylPlus Voluntary Commitment was included in the Rio+20 Registry of Commitments.

"Your cradle-to-cradle approach is exactly what is needed. So, if you look into your supply chain, subsidiaries and other contacts, that kind of conversation and dialogue is part of how we need to do things in the future … Together we must create and catalyze transformation and change," said Ambassador Tomas Anker Christensen, senior advisor at the United Nations Office for Partnerships, at the 2013 Vinyl Sustainability Forum.

What's Next?

The progress of VinylPlus proves that the industry is successfully moving to a truly circular economy model, which puts end-of-life materials back into the production stream, extending the added value of PVC's inherent durability and versatility. Many things remain to be done, of course, but the ongoing efforts of the PVC industry are clearly going in the right direction.

All the solid work done so far is the best springboard to take the industry to the next level. In the words of the European Union's Cozigou, "the PVC industry has a great role to play" in Europe's journey to smart, sustainable and inclusive growth. We must make sure we continue to have the support of the entire value-chain; only together can we continue the journey toward sustainability.

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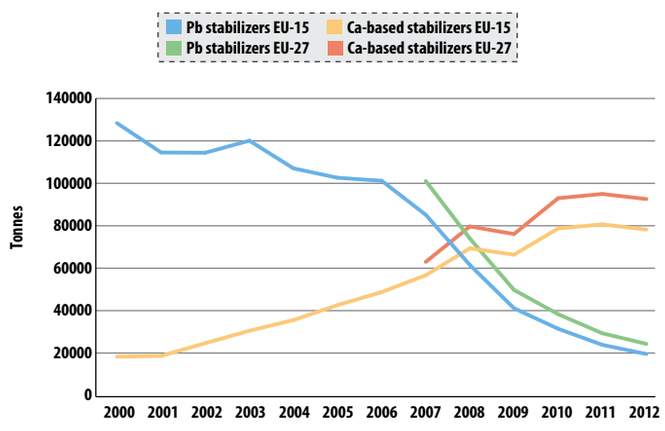
bit.ly/CMI_PVC

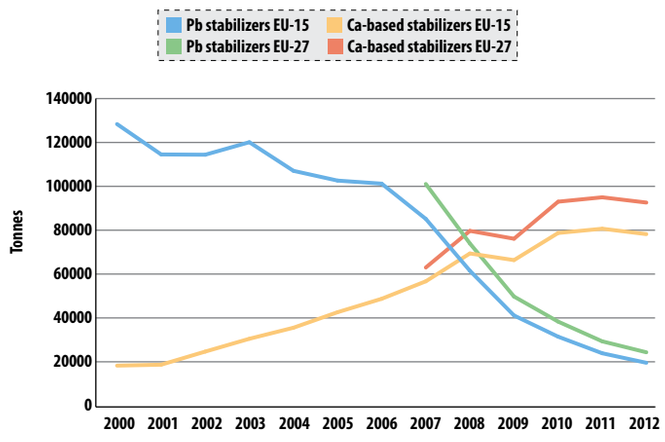
PVC recycled within the Vinyl 2010's and VinylPlus' frameworks Fig. 1



Source: VinylPlus © CHEManager Europe

PVC recycled (in tons) within the Vinyl 2010's and VinylPlus' frameworks.

Stabilizers production data Fig. 2
EU-15 & EU-27 (plus Norway, Switzerland and Turkey)



Source: VinylPlus © CHEManager Europe

Stabilizers production date (in tons) EU-15 and EU17 (plus Norway, Switzerland and Turkey).

The East Is Green

Asia's Role in the Commercialization of Bioplastics

Going Green, Going East – Developing more sustainable materials and meeting demand patterns in Asian growth markets are two of today's major challenges for European chemical companies. While Asia will play a critical role in any large-scale commercialization scenario of bioplastics, its regional differences are striking when considering parameters such as feedstock availability, industry infrastructure, customer industries and government policies.

Bioplastics receive an increasing amount of attention by both industry and consumers as one of the main drivers toward a bio-economy. The term bioplastics, however, encompasses a range of polymers that can either be bio-based (at least partially), biodegradable or both. As of today, these materials account for approximately 1.5% of global plastics demand, but it is estimated that they could substitute up to 85% of conventional polymers.

Biodegradable plastics such as starch blends or polylactic acid (PLA) have dominated early bioplastics market development with applications in food packaging, catering products, shopping bags or agriculture. More recently the concept of replacing conventional oil-based plastics such as PE, PP or PET with their bio-based counterparts has gained commercial importance. These "drop-in" solutions focus on durable applications in rigid packaging, health care, consumer goods or automotive sectors and will dominate future capacity additions in the bioplastics industry.

A recent study by Nova Institute forecasts global biopolymer capacities to grow from 3,500 kt in 2011 to approximately 12,000 kt in 2020. New production capacity in Asia alone will be larger than combined additions in the rest of the world. To better understand the drivers behind these projections, it is essential to analyze feedstock availability, industry infrastructure, customer industries and government policies in some of the region's key countries — notably Japan, Thailand and China.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Japan: R&D Cluster

With its high dependency on oil-based naphtha imports, Japan strives to strategically diversify its raw material supply. Its traditionally strong chemical companies, innovative customer industries and environmentally conscious consumers provide fertile ground for development and launch of bio-based material alternatives. Automotive powerhouse Toyota is on the global forefront in committing to the use of bioplastics in applications such as vent louvers or radiator end tanks.

Chemical industry players Mitsubishi Chemical, Mitsui or Teijin are all engaged in bio-based material research projects. Japan, however, lacks the natural resources and agricultural space to become a bioplastics production center on its own. Large-scale investments of Japanese companies are therefore taking place in feedstock-rich regions of the world. Mitsui has entered a joint venture for bio-PE production with Dow Chemical in Brazil, and Mitsubishi Chemical is constructing a bio-PBS plant with its local partner PTT in Thailand.

Thailand: Production Hub

Other investments in Thailand — like the 75 kt PLA monomer plant of Purac — give evidence of the country's ambitions in becoming the major production hub for bioplastics in Asia. Two competitive advantages stand out: Thailand's big agricultural base as a major global cassava and sugar exporter and supportive government policies addressing strategies, standards and incentives in the National Roadmap for the Development of the Bioplastics Industry.

Thailand also boasts a strong upstream chemical value chain including numerous starch, sugar and glucose plants as well as the largest plastics processing industry in Southeast Asia. In terms of sheer size, however, all eyes are on China.

China: Key Market (To Be ...)

China is the largest plastics processer in the world. Since 2010, its annual plastics consumption is larger than that of all European countries combined. It must play a crucial role in any large-scale commercialization scenario of bioplastics. Current bioplastic capacities in China are yet remarkably small at approximately 300 kt and focus almost entirely on biodegradable materials such as starch, PBS and PLA. Local market demand is at present almost negligible.

But interpreting the ongoing Chinese paradigm shift "from rapid development to more inclusive growth," there are at least three major end-user effects driving the market potential for bioplastics in the country:

- Increasing purchasing power and rising environmental consumer awareness
- More sophisticated, value-added products being manufactured in China
- Proliferation and globalization of Chinese brands.

While the first two points have made Western companies adjust their product portfolios to local demands, the last one is too frequently ignored. Chinese companies such as Huawei, Haier, Lenovo and Geely are becoming truly global brands and increasingly receptive to more innovative technologies. They require dedicated marketing efforts and application support from Western chemical suppliers.

In the light of these developments, SusTech Consult conducted a primary survey among more than 100 plastics processing companies in China to analyze their views on current and future use of bioplastics.

Survey Results

Companies participating in the survey were 75% Chinese entities and 25% Sino-foreign joint ventures from different value chain positions: original equipment manufacturers (OEMs), branded converters and custom molders. Primary focus of the survey was on durable applications.

A first finding: Compared with other aspects of "green plastics" such as hazard-free materials, energy efficiency in production or recycling solutions, bio-based polymers are currently still of low importance to plastics processors in China. Notable exceptions were identified in IT, rigid packaging and consumer goods segments.

Only 5% of companies interviewed had used bioplastics in the past. And if so, mainly for testing or special series purposes. Major reasons for not using bioplastics are high material prices and poor performance properties. Furthermore, a striking 18% of respondents stated that the concept of bioplastics was entirely unknown to them. So besides improving cost/performance issues, a key lever for developing the Chinese bioplastics market is investment in customer education. Looking ahead, the key drivers for bioplastics in China are seen as twofold: A stricter legal framework would push the market in the short- to mid-term, whereas increasing consumer demand and related green strategies of end-users will pull the market in mid- to long-term.

Strategic Implications

Bioplastics in Asia are no low-hanging fruit. While Thailand is on the way to become one of two or three global supply hubs for bioplastics, the Asian demand perspective is significantly more difficult to assess. Educating Asian customers along the value chain on bioplastics is a strategic priority. Within this, evolving global brand owners from China constitute a widely unexplored target group for European bioplastic producers.

For in-depth graphics, please see the article online.

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bit.ly/Bioplastics1

Products From Plants

Enabling Sustainable Materials with Biosuccinium Succinic Acid

Bio-Based Building Blocks – The need to reduce dependency on fossil resources, a growing world population and an increased concern for the environment are driving companies to supplement oil-based chemicals with plant-based, sustainable, high-quality chemical building blocks.

Reverdia, the joint venture between Royal DSM and Roquette Frères, produces Biosuccinium sustainable succinic acid, with proprietary green technology. It enables customers to produce bio-based, high-quality materials while at the same time substantially improving their environmental footprint.

In December 2012, Reverdia started operations of the world's first large-scale commercial plant for the production of succinic acid from renewable resources. The facility, in Cassano Spinola, Italy, has an annual capacity of about 10,000 tons and is a step in the company's strategy to even larger production facilities in the near future. The location of a second large-scale plant is open, and global opportunities are being evaluated.

Applications

Biosuccinium succinic acid provides impetus for an entire range of more renewable, sustainable bio-based products. While conventional markets for succinic acid include pharmaceuticals, food, coatings and pigments, Reverdia sees that the production of a high-quality, bio-based succinic acid like Biosuccinium helps to drive the emergence of new applications (fig. 1).

An upcoming market is polybutylene succinate (PBS), a biodegradable polymer, for which the market is expected to grow rapidly, partly driven by global policymaking on single-use consumer products. When PBS is based on Biosuccinium, it can have a renewable content as high as 50% and even 100% if bio-based 1,4 butanediol (BDO) also is used. PBS also shows interesting physical properties, like high elongation/flexibility, good temperature resistance and easy processing. It can be applied in a pure form, but it also represents an ideal blend partner in compounds. Copolymerization with different types and content of co-monomers can obtain a range of properties, which provides many opportunities for the packaging industry and the plastics industry in general.

Other applications include those where adipic acid is the current conventional chemical, a large market with many opportunities such as (nonphthalate) plasticizers, coating and composite resins, and polyester polyols for polyurethanes. Biosuccinium improves the bio-based content of these products as well as the carbon and environmental footprint (fig. 2). Biosuccinium has now been produced for several years and has been tested and validated in several of these applications by numerous customers.

Best-in-Class Carbon Footprint and Economics

Reverdia developed and commercialized a unique, proprietary, low pH yeast technology to convert sugars into succinic acid. The novel process is simple, stable, very energy-efficient, and generates less waste and impurities than the bacteria-based technologies that are being used in alternative routes for bio-based succinic acid (figure 4). Reverdia uses this yeast technology to produce Biosuccinium at best-in-class carbon footprint and economics. The best-in-class carbon footprint is also supported by the Copernicus Institute at Utrecht University in the Netherlands. It conducted a Life Cycle Assessment study, which compared various production methods in detail, assuming all other things are equal (especially the energy mix and feedstock usage). The study found that the yeast-based fermentation process at low pH, with direct crystallization, as used by Reverdia to produce Biosuccinium, has significantly lower greenhouse gas emissions than other fermentation routes or petrochemical routes (fig. 2). The results of this LCA study are published as an early view in Wiley Online Library (August 2013).

Reliable Company, Reliable Product Quality

Reverdia combines DSM's expertise in materials sciences, life sciences and biotechnology with Roquette's know-how in plant-based raw-material processing. These two large international companies have been developing, producing and supplying bio-based products globally for decades.

Reverdia benefits not only from the capital and expertise of both mother companies but also from their production facilities. Biosuccinium formerly was produced in a demonstration plant on the Lestrem site of Roquette in France, and the production facility in Cassano is again backward integrated with a Roquette biorefinery for on-site production of the starch feedstock. The Cassano site benefits from the experience gained in the demonstration plant where Biosuccinium was produced for more than two years. Reverdia's first large-scale commercial plant is using the same low pH yeast technology as was used in Lestrem and can therefore also deliver on product quality promises.

For more photos and graphics, please see the article online.

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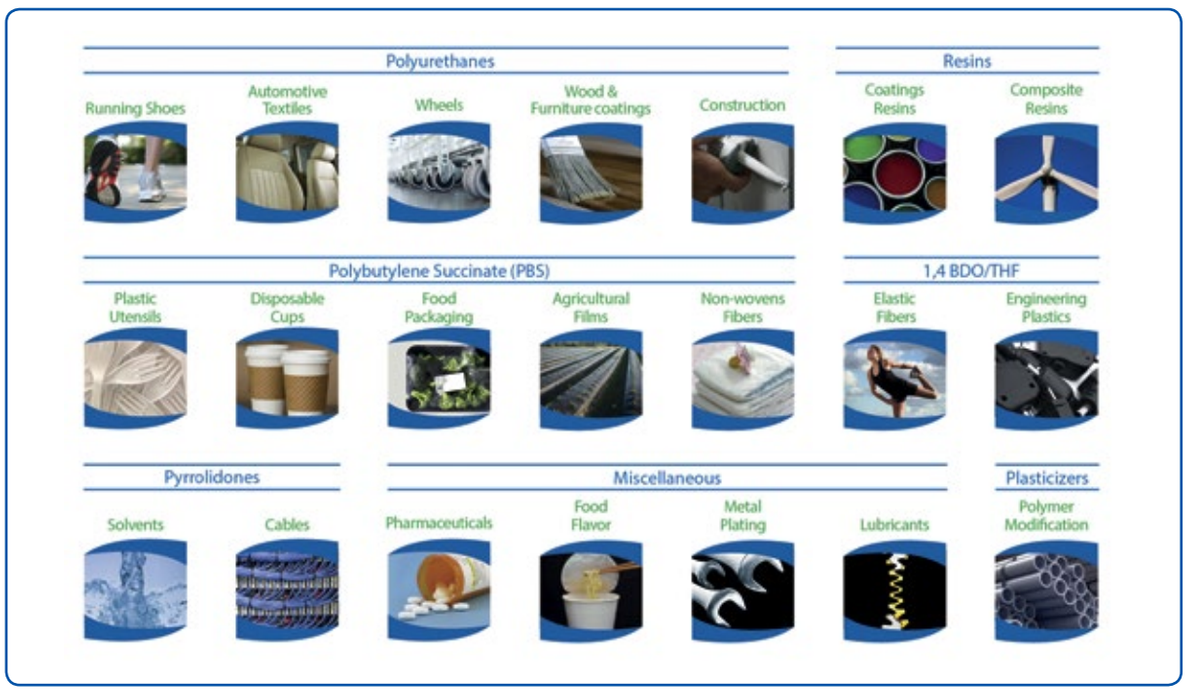
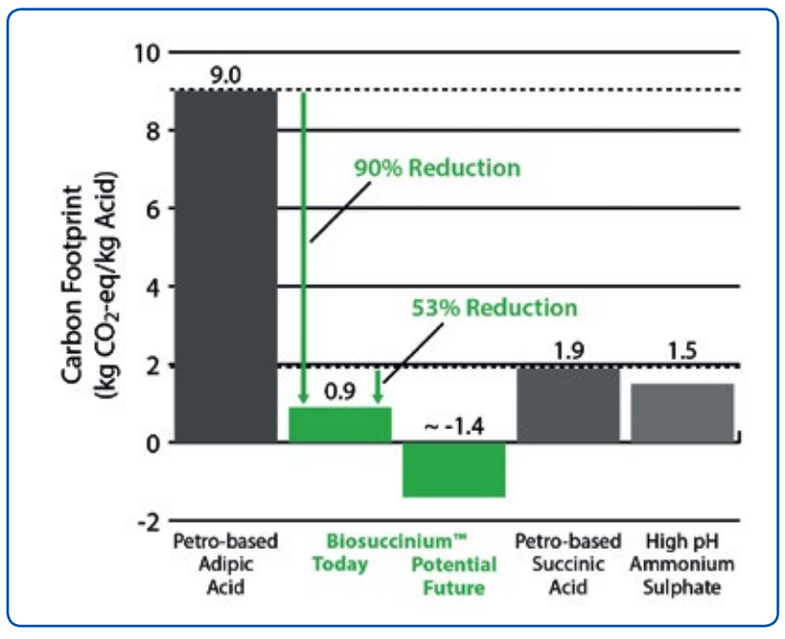


Biosuccinium market opportunities



Reduction in carbon footprint with Biosuccinium

EVENTS

Rx-360 Symposium, Oct. 30, Lisbon

Rx-360 is a not-for-profit consortium led by volunteers from the Pharmaceutical and Biotech industry including both manufacturers and suppliers. The purpose is to enhance the security of the pharmaceutical supply chain and to assure the quality and authenticity of the products moving through the supply chain. Rx-360 Symposium will provide attendees an update on the consortium's activities, provide perspectives on supply chain security from leading global logistics providers, and highlight ways to combat falsified medicines, focusing on the EU's FMD as well as enforcement resources.

▶ www.rx-360.org

2013 ISPE Annual Meeting, Nov. 3-6, Washington, DC

Pharmaceutical quality metrics will be a key discussion topic between industry leaders and international regulatory agencies at the 2013 Annual Meeting of the International Society for Pharmaceutical Engineering (ISPE). The session, entitled "Quality Metrics Outcomes: Conversations with the FDA," will take place during the Executive Series track on 4 November. The industry's first public conversations on quality metrics took place at ISPE's second annual CGMP Conference in June 2013 during a capacity-attendance workshop-style session. The continuing discussion will feature presentations from the ISPE Quality Metrics working groups on potential metrics for Batch Failure Rates and OOS/Lab Failure Rates, among other new ideas.

▶ www.ISPE.org

3rd South America Surfactants HPC Markets Conference, Dec. 2-3, Sao Paulo

Tailored to provide an overview of the surfactants market in Latin America, the event provides specific updates on the home & personal care market, sustainability trends, latest technological innovations & raw material solutions and shares perspectives from leading Latin American producers, retailers and end users. Four sessions will present trends marking the Brazil and LATAM home care markets: Opportunities & Development Of Home Care Market in Brazil, Challenges in the Institutional Cleaning Market, Latin America Surfactants Outlook, Competitive Strategy in South America Surfactants Industry. Attendees will gain insights on the surfactants market in South America and meet leading oleochemicals & surfactants producers, intermediate & feedstock suppliers, personal & homecare manufacturers, FMCG producers, equipment & technology suppliers, and more.

▶ www.cmtevents.com

9th Plastivision India 2013, Dec. 12-16, Mumbai

India's second largest plastics show Plastivision India 2013, organized by The All India Plastics Manufacturers' Association (AIPMA), will witness the participation of over 1,500 companies from India and 30 other countries and expect visits by over 100,000 businessmen and other key stakeholders. AIPMA has invited business delegations from ASEAN countries, Middle East, Africa, Latin America and Eastern Europe. The trade show features finished plastics products, plastics processing machinery, mold-making, design and application development, and automation and engineering equipment.

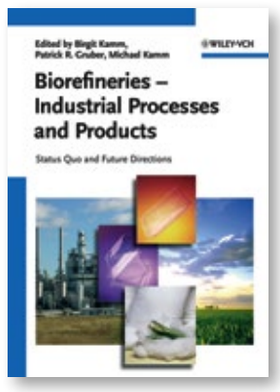
▶ www.plastivision.org

Techtextil Middle East Symposium, Jan. 19-21, Dubai

With the launch of the Techtextil Middle East Symposium and the associated Techtextil Pavilion, the Messe Frankfurt is expanding its successful conference brand. In 2014 Techtextil, the leading trade fair for the technical textile and nonwovens sector will take its first steps into the growing markets of the Middle East. Both events will be held concurrently with Intersec 2014, the Leading International Trade Fair for Safety & Security. Over 1,000 exhibitors and more than 22,000 trade visitors are expected to take part in the 16th edition of the fair. The original Techtextil, is held biennially in Frankfurt, Germany. Techtextil events in China, India, Russia and the USA are leading fairs or most important forums for technical textiles in their individual regions.

▶ www.techtextil.com

Biorefineries – Industrial Processes and Products

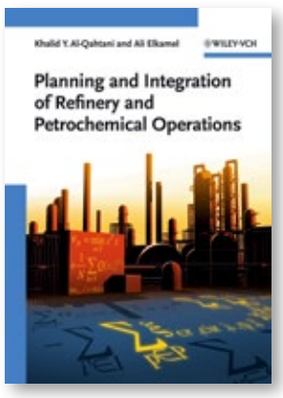


This book is devoted to biorefineries and biobased industrial technologies, and, as such, is directed towards the technological principles of biorefineries, green processes, plants, concepts, current and forthcoming biobased product lines, as well as the economic aspects. Since the hot topics of green chemistry and green processes are of a multidisciplinary interest, this book will benefit the whole spectrum of the process industry, including chemical engineers, process engineers, apparatus construction engineers, chemical industry, chemists in industry, and biotechnologists.

The editors and authors are all internationally recognized experts from industry and academia, including Dr. Patrick Gruber, the former Vice President and Chief Technology Officer at Cargill Dow, winner of the U.S. Presidential Green Chemistry Award and holder of more than 40 patents.

▶ Biorefineries - Industrial Processes and Products
Birgit Kamm, Patrick R. Gruber, Michael Kamm
Wiley-VCH
1. Edition July 2010, Price: €135
ISBN 13: 978-3-527-32953-3

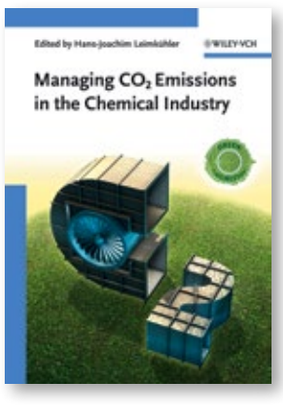
Planning and Integration of Refinery and Petrochemical Operations



Divided into three main sections, this book familiarizes readers with the area of planning in petroleum refining and petrochemical industry, while introducing several planning and modeling strategies encompassing single site refinery plants, multiple refinery networks, petrochemical networks, and refinery and petrochemical planning systems. It provides an insight into possible research directions and recommendations for the area of refinery and petrochemical planning. Several appendices are included to explain the general background necessary, including stochastic programming, chance constraint programming, and robust optimization.

▶ Planning and Integration of Refinery and Petrochemical Operations
Khalid Y. Al-Qahtani, Ali Elkamel
Wiley-VCH
Price: € 79.90
ISBN 13: 978-3-527-32694-5

Managing CO_2 Emissions in the Chemical Industry



This reference and handbook on this hot topic covers the technical and administrative aspects of CO_2 emissions, with special reference to the chemical and petrochemical industry. It discusses energy efficient design, cultural aspects and future developments, answering questions along the way as:

How can I measure and demonstrate the CO_2 emissions linked to my production?

How can I benefit from CO_2 neutral investments using the UNFCCC frame?

How can I reduce or avoid CO_2 emissions by technical measures and new processes?

If CO_2 emissions cannot be avoided, how is the capture and storage of CO_2 technically and economically feasible?

What are the upcoming technical developments regarding CO_2 reduction?

▶ Managing CO2 Emissions in the Chemical Industry
Hans-Joachim Leimkuehler
Wiley-VCH
Price: €139
ISBN 13: 978-3-527-32659-4

PEOPLE

Alexander Wessels

Alexander "Xander" Wessels has joined Archroma, the new company consisting of the former Textile Chemicals, Paper Specialties and Emulsions businesses of Clariant as new CEO. Wessels has almost 25 years of chemical, pharmaceutical and process industry experience and has spent the past seven years at DSM, where in his most recent position he was President and CEO of DSM Pharmaceutical Products. Previously, he held various management and executive positions at Unilever, Quest, ICI, and Campina. The Dutch native holds an MSc in Molecular Sciences from Wageningen University in the Netherlands, and both an MSM and MBA from the Kranert Business School of Purdue University (USA) and Tilburg University (NL).

Dr. Stefan Peterli has been appointed to CEO of CU Chemie Uetikon starting Oct. 1. The Ph.D. chemist has more than 20 years of experience in the research-based and generic pharma and chemical industry. Peterli (48) filled leadership positions in marketing, sales, business development, as well as research and development and project management. Jointly with CFO/COO **Thomas Seeler** he will lead the fine chemical and API manufacturer to accelerate international expansion of the Lahr, Germany based enterprise. Prior to his appointment at CU Chemie Uetikon, Peterli was a member of the management team of Pharmazell. Earlier he worked for Dipharma, Lonza and Siegfried, respectively.

Frank Wright

Frank B. J. Wright has been appointed to the management team of Altana's subsidiary Byk-Chemie from Oct. 1. The addition of Wright, previously managing director of the rheology business of Rockwood underlines the particular importance attributed to the acquisition of the business by Altana. Wright will actively accompany and support the integration process of the rheology business into the Byk Additives and Instruments division. In his function as new managing director of Byk, Wright's responsibilities will include the management of the new Oilfield business line and the existing Industrial Applications business line.

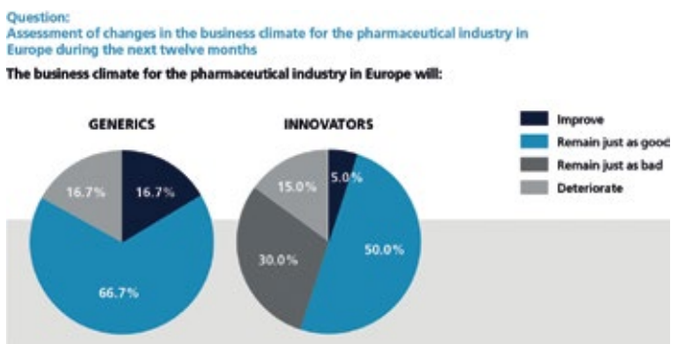
Martijn van Koten joins Borealis'executive board as executive vice president operations effective Nov. 1. He succeeds **Herbert Willerth** who will forthwith, as deputy CEO, focus on Borealis' Middle East and Asia activities. Van Koten joins Borealis after a distinguished career of more than 19 years at Shell, which has given him broad experience covering the disciplines of Manufacturing, Technical Service, R&D and Strategic Development, in his most recent role at Shell he served as VP Manufacturing East, based in Singapore. Van Koten has a Masters degree in Chemical Technology from Delft University of Technology, The Netherlands.

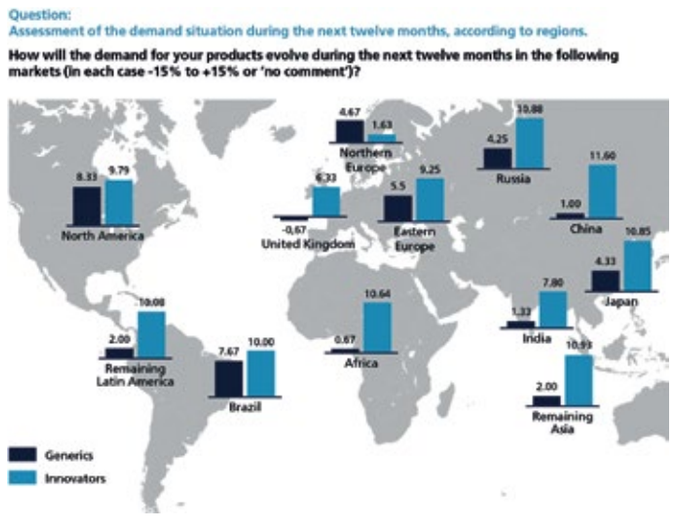
Olivier Brandicourt

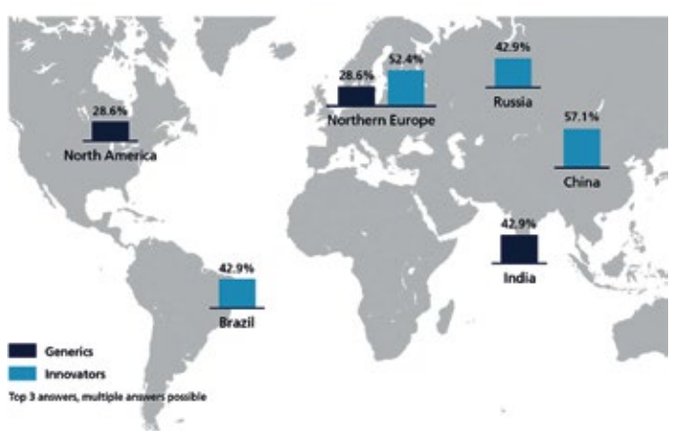
Olivier Brandicourt has been appointed chairman of the board of management of Bayer HealthCare and member of the Bayer executive council effective Nov. 1. Since March 2013, Prof. Wolfgang Plischke has led Bayer HealthCare on an interim basis in addition to his existing duties as a Bayer Board Member. Brandicourt has 25 years of experience in the pharmaceutical industry, including executive responsibilities in France, the United States, Canada and the UK. He has been a member of the Executive Leadership Team of Pfizer for the last three years. Brandicourt holds a medical degree with a subspecialty in infectious diseases and tropical medicine, as well as a master's degree in biology from Paris 12 University, France.

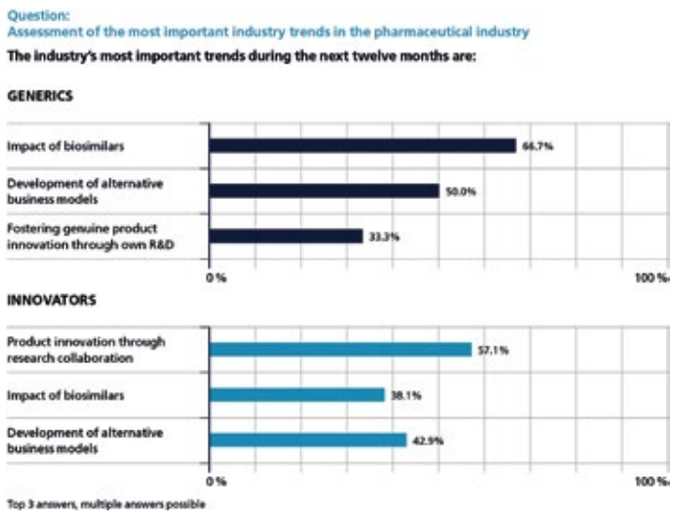
Jason Fox has been named director of Evonik's Oil & Gas Group, which the German specialty chemicals company formed to boost the resource-efficiency of products it supplies to the oil and gas industries. Fox joins Evonik after more than 10 years at oilfield chemicals company Nalco Champion. He earned a bachelor of arts from the University of Calgary and a master of business administration from Athabasca University in Canada.

Camelot Management Consultants Pharma Management Radar Survey









In August and September 2013, the Pharma Management Radar expert panel, consisting of more than 80 executives from globally active pharmaceutical companies based in 16 countries, was interviewed. After the surprisingly positive estimation of the current business climate registered in the first Management Radar survey published half a year ago, the experts generally remain satisfied. This particularly applies to the generics executives, all of whom rate the business climate as "mostly good."

Markets Bouncing Back

Considering the business climate in the next 12 months, the overall estimation has brightened up slightly, especially among innovators who had been considerably more pessimistic at the beginning of this year. It seems as if at least some of the innovators had found a way to cope with the "additional benefit/outcome topic" and thus have developed a slightly more positive assessment in the course of the year. While the pharmaceutical industry is still suffering from the Eurozone crisis in various regions, some of the established markets outside Europe seem to be coming back: Demand expectations for Japan and North America — which may also be positively affected by re-elected President Obama's health-care reform — are showing some considerable growth.

Development Of Global Demand

A striking difference between generics' and innovators' demand expectations can be found in emerging regions such as China and Africa, where the generic segment is much less optimistic. This clearly has to do with the fact that in these regions innovative products are available mainly for wealthy self-pay patients who can afford even higher prices than are paid by the healthcare systems in developed countries. However, the poor majorities of these emerging regions can't afford more than a minimum price, thus making the situation rather unattractive for the producers of generics compared to that in the established markets.

Regional Investment Plans

When it comes to regional investment plans for the next 12 months, the executives' answers differ considerably from their demand expectations. Eastern Europe, Russia and North America have lost some of their investment attractiveness. The top destinations for future investment are now China, Northern Europe and Brazil, when taking generics and innovators together. Looking at the two segments separately, India is the most important investment region for generics, whereas innovators prefer China and Northern Europe. It shows that there is a slight shift back toward the established markets. The BRIC markets seem to have lost a bit of their former growth potential and attractiveness.

Industry Trends

Asked for the most important industry trends in the pharmaceutical industry, two-thirds of the generics executives name the influence of biosimilars. Given that the biosimilars business requires far more R&D than the traditional generics business, it is logical that the R&D aspect is seen as an important trend by as many generics as innovators. This trend is going hand-in-hand with the development of alternative business models, which also plays a major role for generics. The latter are driven by pricing pressure that makes vendors constantly look for new marketing and distribution methods in order to stabilize their business.

— Michael Jarosch and Dr. Axel Sinner, Camelot

See also page 16

Every Second Counts – When rescue helicopters take off, a few seconds can make all the difference. Whether they're responding to a car accident in a city center, flying on a rescue mission in the mountains, or battling strong winds at sea—the extreme conditions place very high demands on the material. The Eurocopter EC135 has proven its reliability in air rescue operations thanks to its optimal safety and stability. The rotors are stable, yet flexible and lightweight; the engines are reliable and powerful. Another safety element is invisible: the front windscreen made from Plexiglas from Evonik. It provides a panoramic view and protects pilots from UV rays, offering them clear visibility and maximum safety during a rescue mission.

Coming Up in the November issue of CHEManager Europe

- Interview with Danish author and academic Bjørn Lomborg
- Successful Switch to Membrane Technology: WeylChem PPC in Thann, France by Lejla Skaljic,Weylchem
- The Influence The Proliferation Of Shale Gas On The Global Petro Industry by Michael Mbogoro,Frost
- The Chemical Industry in China and the Middle East: Cooperation or Conflictby Dr. Kai Pflug, Management Consulting — Chemicals
- Downstream On an Up in Azerbaijan: Investment Opportunities in the Petrochemical Industry by Zaur Mammadov, Sumgait Chemical Industrial Park
- Next Generation Manufacturing: Holistic Business Approach Supports 'Industry 4.0' Principles by Scott Bolick, SAP
- Minimize Carbon Footprint and Maximize Supply Chain Value by Laura Rokohl, AspenTech
- And much more!

Hot off the press on Nov. 14
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This issue of CHEManager Europe contains the special supplement

ViP – VISIONS IN PLASTICS
A SPECIAL PUBLICATION OF CHEMANAGER & CHEMANAGER EUROPE

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