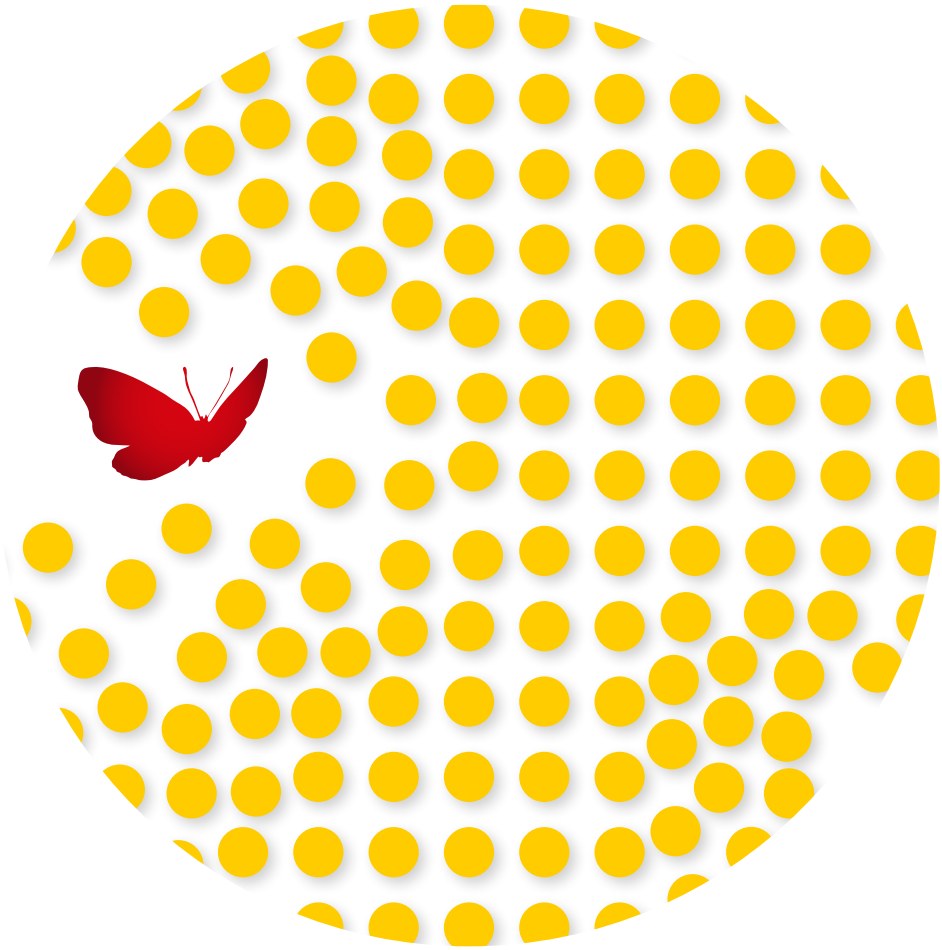

THE RESILIENCE IMPERATIVE:

REINVENTING HEALTHCARE SUPPLY CHAINS

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DHL SUPPLY CHAIN

The global life sciences and healthcare (LSH) industry is at a turning point.

It faces a constellation of challenges that are occurring simultaneously and – taken together – constitute a seismic shift in the very nature of business.

Shrinking margins, escalating cost pressures, burgeoning regulatory and compliance requirements, changing product characteristics and growing consumerism are transforming the LSH business paradigm. What is emerging is a business model that looks and acts like the consumer goods industry, where the customer – not the manufacturer – holds the power.

For most industries, experiencing two or three complex challenges at one time is enough to cause major disruption. But the LSH sector is contending with far more issues. The net effect is that business as usual is over.

The old LSH business model, and the supply chain that supported it, is no longer fit for purpose.

Needless to say, the stakes in the new normal of LSH are enormous. So large, in fact, that the U.S. Congress was willing to shut down the entire federal government for two weeks while it fought over healthcare reform issues. That shutdown, according to Standard & Poor's, cost the U.S. economy more than $24 billion.

Given this context, what are some of the forces at play in the global LSH sector? The list below provides a partial snapshot:

- Patents on so-called blockbuster drugs are expiring (the patent cliff), eliminating billions of dollars of profit as generic substitutes flood the market
- Rising healthcare costs are prompting governments and insurance providers to demand drastic cost cuts
- Healthcare policy-makers and payers are increasingly mandating what doctors can prescribe
- Clinical advances enable more distributed care – much of it in the home
- An aging world population is consuming more health resources, straining government budgets
- Chronic diseases caused by obesity, smoking and other lifestyle habits are rising at an alarming rate
- Medicine counterfeiting has become big business, and kills hundreds of thousands of people each year
- Geographically extended LSH supply chains dramatically increase the risk of business disruption
- Regulatory regimes around the world are increasingly complicated, with no global standards and individual country requirements
- Pandemics like the H1N1 influenza outbreak which killed up to an estimated 575,400 people
- Rapid growth in emerging markets is taxing the LSH supply chain.

The old LSH business model, and the supply chain that supported it, is no longer fit for purpose. The new LSH environment requires a new supply chain – one that delivers robust global management capabilities, reduces costs and hard-wires in the resiliency needed to support the challenges of global health.

The resilience imperative

The LSH sector finds itself in the position of needing to re-think its entire economic model, and find ways to slash costs across the board in order to maintain share in a marketplace that is no longer either willing or able to fund profit margins that ranged as high as 40 to 80 percent.

The convergence of forces listed above makes one thing abundantly clear. The traditional and currently operating LSH supply chain is not built to deliver the agility, flexibility, cost reduction and resiliency required in this new environment. Simply put, a new, leaner, more resilient LSH supply chain is the key to future success for global LSH enterprises.

Part 1: Current state and driving trends

The emerging LSH supply chain must tackle a difficult agenda that includes a wide array of issues. These issues can be grouped into three high-level categories:

- Patent cliff, changing products and profit erosion
- Emerging markets, demographic shifts and healthcare policy
- Regulations, compliance and product integrity.

We discuss each of these three areas, and their myriad of complexities, in the following section. To start, though, we provide some statistical context on the size and scope of the global LSH industry.

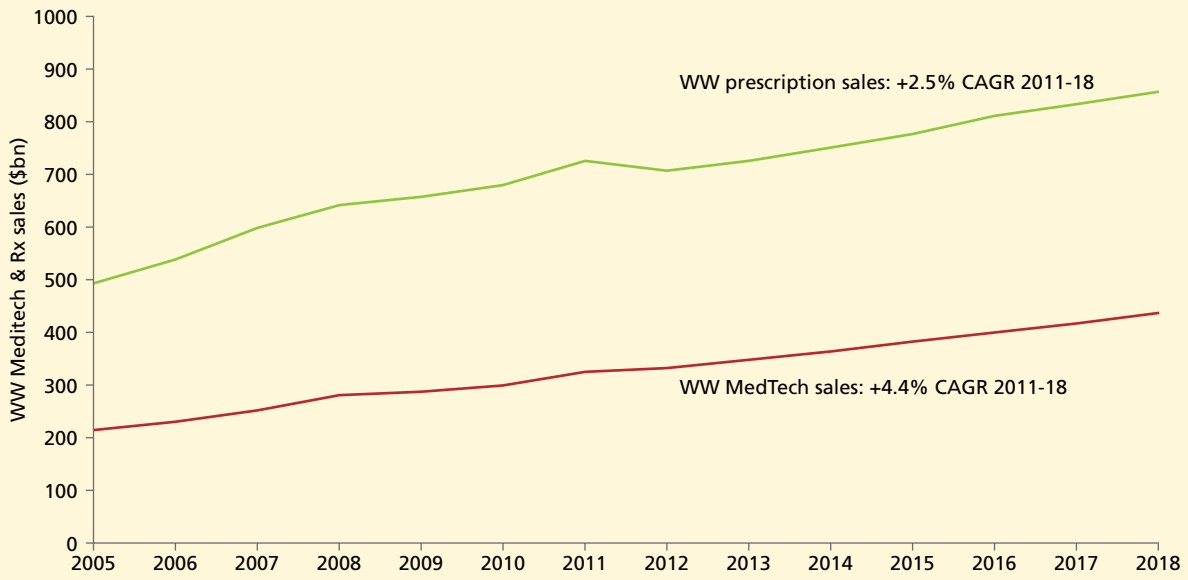
According to the World Health Organization, global health expenditure has reached $4.5 trillion per year. Expenditure on pharmaceuticals accounted for some $714 billion of this total in 2012.[1] By 2020, the global pharmaceutical market could be worth nearly $1.6 trillion.[2]

Worldwide sales of medical devices, the other component of the life sciences and healthcare sector, are expected to reach more than $440 billion in 2020, a compound annual growth rate (CAGR) of 4.4 percent (versus 2.5 percent for prescription drug market).[3] Because of this higher growth rate, medical device sales are forecast to represent over one third of product spend by 2018.[4]

"[Medical devices] will continue to benefit from emerging market investments that are lifting standards of care, while cost conscious developed markets will continue to invest in more efficient machines, systems and procedures, which offer less hospital time and better patient outcomes".[5] Figure 1 shows sales projections for the top 10 medical device companies in 2018.

[1] EvaluatePharma, Returning to Growth: World Preview 2013, Outlook to 2018, 2013, p.7.
[2] PwC, From Vision to Decision, Pharma 2020, 2012, p.4.
[3] EvaluateMedtech, World Preview 2018 – A Consensus View of the Medical Device and Diagnostic Industry.
[4] Ibid, p.8.
[5] Ibid, p.3.

Figure 1: Worldwide medical device vs. prescription drug sales 2005-2018



Source: EvaluateMedTech, 2013.

Patent cliff, changing products and profit erosion

Worldwide prescription drug sales fell by 1.6 percent to $714 billion in 2012. Loss of patent protection on a number of major drugs, and fiscal austerity hitting governments around the world, contributed to this unprecedented contraction. Value-driven governments, commissioning bodies and payers have constrained decision-making by physicians on which drugs are prescribed and which drugs are granted access to specific markets. These entities favor the proven, low-price generics where these are available that now saturate the marketplace.[6]

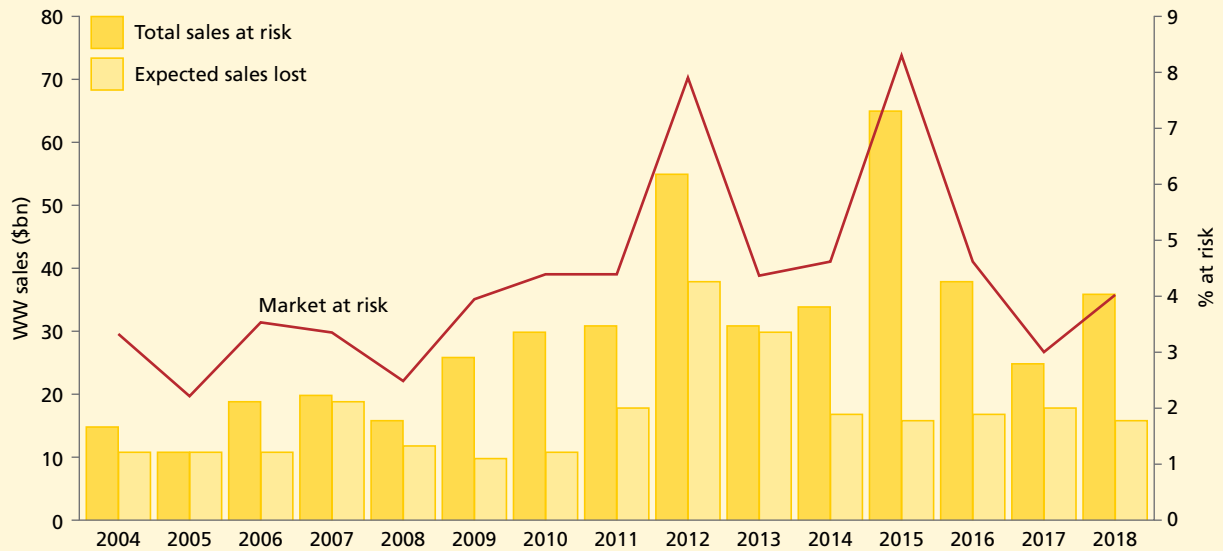
The sales reduction as products come off patent and generic competition enters the market is staggering. In 2012, $38 billion of sales were lost as a result of expired patent protection, including: Lipitor losing $5.6 billion, Plavix $4.5 billion, Seroquel $3 billion and Zyprexa $2.9 billion against an at risk level of $55 billion, a 70 percent reduction.[7]

The profit decline from patent expirations is not over. A report from EvaluatePharma estimates that between 2013 and 2018, $230 billion of worldwide drug sales are at risk from generic erosion following patent expiry.

Some companies could see sales reductions of up to 80 percent on blockbuster prescription drugs according to Saul Resnick, Vice President, Life Sciences and Healthcare, DHL Supply Chain – Asia Pacific, Middle East and Africa (APMEA). "Because of their far lower price points, the generics replacing the patented medicines, require a highly cost effective supply chain that also delivers fast, reliable speed to market. From a supply chain profile perspective, generics act more like fast moving consumer goods than traditional pharmaceuticals. Supply chain cost as a percentage of sales must be low. This means the industry, including manufacturers and distributors, must turn supply chain fixed costs into variable costs if they are to remain profitable and agile."

[6] Jonathan Anscombe, Michael Thomas, Jonathan Plimley, The Journey Back to Health for Drug Manufacturers, Chain Drug Review, August 5, 2013.
[7] EvaluatePharma, Returning to Growth: World Preview 2013, Outlook to 2018, June 2013, p.3.

Figure 2: Worldwide sales at risk from patent expiration 2004-2018



Patient Analysis: 'Total Sales at Risk' represents the worldwide product sales in the year prior to patient expiry but allocated to the year of expiry. e.g. Plavix had sales of $7.1bn in 2011, this is shown as 'At Risk' in 2012.
Source: EvaluatePharma, June 2013.

At the same time that this profit erosion is occurring, LSH companies face increasing pressure from direct customers, governments, insurance companies and consumers to reduce prices. "Once formularies and reimbursement rates are locked down, product negotiations could move into the realm of the medical administrator or other institutional purchaser, a non-caregiver who becomes the gatekeeper into the provider organization."[8]

Doctors are losing purchase decision-making power especially over devices that are more readily substituted. Hospital administrators and patients will increasingly make the decisions about these products.

Consumers will play a bigger role in healthcare decisions and choices, reflecting a switch in mindset from being "patients" to "consumers." Armed with greater access to product information, patients are better informed about drugs, products, devices, procedures, treatment options and healthcare providers. As a result, they are exercising a greater degree of control over their healthcare decisions, particularly in developed markets.

Three factors are driving this trend toward consumerism: 1) technology – mobile applications will enable comparison of treatment options, costs and the list of providers who adhere to best practices; 2) coverage – high-deductible plans and a growing

[8] Sanjay Behl, Terry Hisey, Ralph Marcello, Moving Target: Life Sciences, Healthcare Reform and the New Marketplace, Deloitte Review 2011, p.118.

individual insurance market, as well as private healthcare for the middle classes in developing markets, is expected to drive price and quality sensitivity; and, 3) transparency – regulators will require increased access to performance data from health plans, hospitals, drug manufacturers, long-term care providers and physicians.[9]

As LSH companies adapt to these pressures, one trend which could mitigate the profit erosion issue is the changing nature of pharmaceutical products themselves. Companies' product portfolios are evolving away from sole reliance on blockbuster prescription drugs, toward more structurally complex biologics – e.g., monoclonal antibodies, therapeutic proteins, immunotherapies, gene therapy and vaccines.

Consumers will play a bigger role in healthcare decisions and choices, reflecting a switch in mindset from being "patients" to "consumers."

Biologics are created through biological processes rather than being chemically synthesized. In 2018, Evaluate-Pharma expects that about 50 percent of sales in the top 100 products will be generated by biological products. These products generally have a lower risk exposure from sales erosion from bio-similar competition than small molecule drugs, due to manufacturing complexities and the requirements to show bioequivalence.

This evolution toward biologics carries significant supply chain implications. Biologics are frequently extremely high value – i.e. treatment costing over $1,000 per dose is not uncommon, meaning that single bulk shipments can be worth upwards of $50 million. Close and careful management of these costly shipments is essential to profitability as well as continuity of supply, due to the long manufacturing lead times. This means that a risk based approach must be taken.

These medicines also are very sensitive to humidity and temperature, and must be handled within very specific tolerances. Failure to maintain appropriate conditions at any point in the supply chain can mean the loss of a shipment. This is not limited to pharmaceuticals; some medical devices and diagnostics products are also condition sensitive.

[9] Deloitte Center for Health Solutions, Health Care Reform Memo, http://www.deloitte.com/view/en_US/us/Insights/Browse-by-Content-Type/Newsletters/health-care-reform-memo/eae2a4232e41c310VgnVCM3000003456f70aRCRD.htm, January 2013.

Emerging markets, demographic shifts and healthcare policy

Collectively, Canada, France, Germany, Japan, the United Kingdom and United States still generate 59 percent of the LSH industry's total revenues. But that ratio will slowly change as huge emerging markets such as China and India expand access to healthcare services and products.[10]

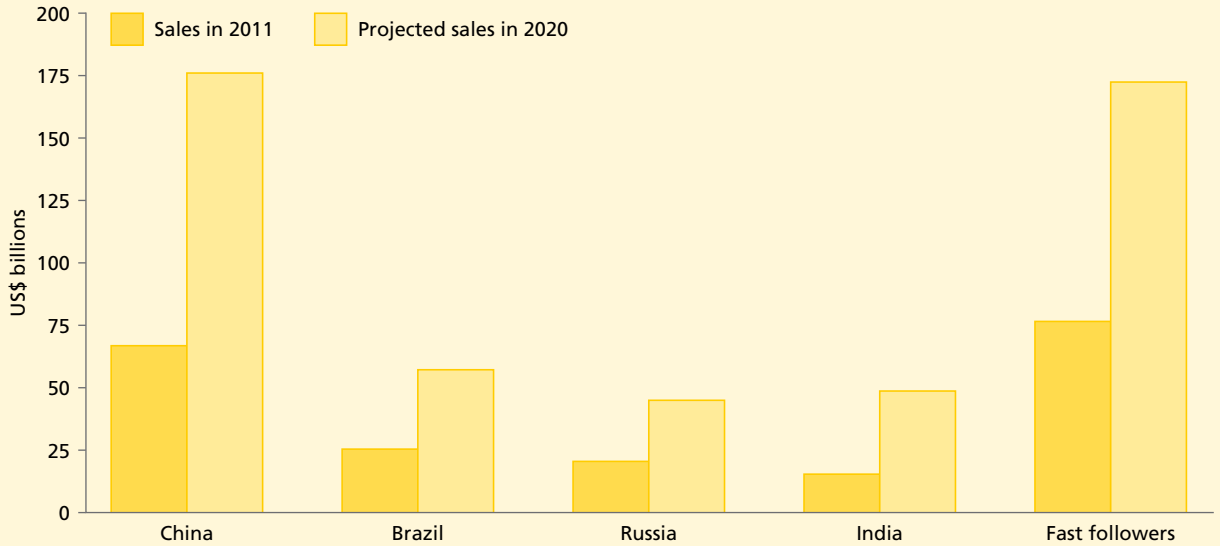
Thus, it is no surprise that LSH companies see emerging markets as key to their future. While growth in the mature economies is sluggish for LSH companies, the high-expansion economies are another matter. For example, pharmaceutical sales in the BRIC countries (Brazil, Russia, India and China) rose by 22.6 percent in 2011,[11] with these markets expected to exceed $300 billion by 2020.

Many of the growth countries are improving access to healthcare. Mexico, for instance, just completed an eight-year drive to provide universal healthcare services to 52.7 million uninsured people – up from just 5.3 million in 2004. China has launched a $125 billion program to extend health insurance coverage to more than 90 percent of its population, most of which has never had insurance before – a program that is straining all aspects of the healthcare delivery system.[12]

However, the growth markets come with some enormous challenges, including their geographic size, cultural diversity, underdeveloped infrastructure, fragmented distribution systems, weak regulations and poor enforcement. While income levels are rising and the ranks of the middle class in these regions are forecast to more than double from 1.7 to 3.6 billion by 2025, patients typically must fund a larger share of their own healthcare costs than patients in the mature economies. And even in the BRIC countries, where the rate of expansion is fastest, per capita expenditure on healthcare is far too low to support biologics priced at many thousands of dollars.[13]

[10] PwC. From Vision to Decision Pharma 2020. p.8.
[11] Ibid, p.5.
[12] Ibid, p.5.
[13] Ibid, p.19.

Figure 3: Rising demand for medicines in fast-growing markets



Notes: (1) All sales are expressed in US dollars at constant exchange rates; (2) The fast followers include Argentina, Egypt, Indonesia, Mexico, Pakistan, Poland, Romania, South Africa, Thailand, Turkey, Ukraine, Venezuela and Vietnam.
Source: PwC, From Vision to Decision, Pharma 2020, 2012, p.18.

In their efforts to serve emerging markets, therefore, LSH companies are adopting variable strategies that range from providing a full portfolio of their products based on positioning as an innovation leader; or going for the volume-value end of the spectrum, and offering a narrower array of products at lower, differential prices. Obviously, this range of strategies requires appropriately tailored supply chains with cost and service structures matched to product portfolios and margin points.

At the same time, these supply chains must cope with a complex and highly variable regulatory environment, taxation issues and import regulations – all of which complicate working across borders. Physical infrastructure – roads, ports, transport capacity, distribution space and delivery networks – can also be highly problematic, especially outside of the major cities. "Serving emerging markets is a complex undertaking," notes one pharmaceutical company supply chain head. "You have so many different regulatory requirements, so many cross-border issues, so many compliance issues – not to mention the physical infrastructure challenges and security. Simply getting goods from point A to point B within a country safely and in proper condition can be a huge challenge."

As emerging markets expand healthcare to more of their population, they face the same issue currently troubling mature economies: the fact that healthcare expenditures are consuming a rapidly increasing share of gross domestic product (GDP). While there are a number of reasons for this, two in particular stand out.

Firstly, the human population is ageing at a truly stunning pace. Within 35 years, there will be more people alive who are older than 60 than there are people younger than 15. By the 2050s, well over one-third of the adult populations of Spain, Germany, Japan, Italy and Russia will be older than 60. For the rest of the 21st century, the fastest-growing consumer group in the world will be people over the age of 60.[14]

[14] AT Kearney and the Consumer Goods Forum, Understanding the Needs and Consequences of the Ageing Consumer, 2013, p.2.

In the United States, during the next 25 years, the number of people aged 65 years or older will double to about 72 million (about 20 percent of the population).[15]

In China there is a similar picture where almost one third of the country's population, or 438 million, will be over 60 by 2050, more than double the current number.[16]

Secondly, concurrent with the ageing trend, the world is seeing a major shift in the leading causes of death for all age groups – from infectious diseases and acute illnesses to chronic diseases and degenerative illnesses, including diabetes, cancer and heart disease. Here again, treatment for these conditions consumes more healthcare resources over a far longer period of time.

From a supply chain perspective, these two trends have not only increased the amount of products moving through the LSH channel, but have created new and more dispersed distribution outlets. The supply chain must now be able to deliver needed products to hospitals, specialist centers, clinics, pharmacies, retail stores and individual homes. In emerging countries, the challenges of reaching consumers outside of the major metropolitan areas can be challenging and expensive.

[15] Centers for Disease Control and Prevention, U.S. Dept. of Health and Human Services, The State of Aging & Health in America 2013, p.ii.
[16] AT Kearney and the Consumer Goods Forum, 2013.

Regulations, compliance and product integrity

On the subject of compliance, one issue has risen to the top of the LSH industry's concerns agenda – counterfeiting.

In June 2012, Angola customs agents conducting a routine search of cargo shipped from China, found 1.4 million packets of counterfeit Coartem, a Malaria medication. Enough to treat over half of Angola's annual Malaria patients.

Fueled by easy internet sales, global supply routes and minimal punishments, counterfeit prescription drugs are an exploding industry, with an estimated market worth $75 billion a year worldwide. Long the scourge of developing countries, fake drugs are now appearing in the United States, as well as other tightly regulated markets. In 2012, a counterfeit version of the cancer drug Avastin was widely distributed in the U.S., and a fake version of the ADHD drug Adderall, in high demand because of a shortage, arrived in the U.S. through internet pharmacies.[17]

> *The World Health Organization estimates that 200,000 people a year die because ineffective, fake, and substandard malaria drugs don't clear their systems of the parasite.*

Unlike fake consumer products, counterfeit drugs can kill people. While the full impact of counterfeit drugs on human health and mortality is difficult to tally, examples of deaths from fake drugs abound. For example, the World Health Organization estimates that 200,000 people a year die because ineffective, fake, and substandard malaria drugs don't clear their systems of the parasite. Counterfeit drug incidents around the world have caused an estimated 700,000 deaths from malaria and tuberculosis alone, reports the International Policy Network.

[17] Barbara Moran, Cracking Down on Counterfeit Drugs, NOVA http://www.pbs.org/wgbh/nova/next/body/uncovering-counterfeit-medicines/, August 20, 2013.

Counterfeit or adulterated products in the LSH supply chain are a grave concern in the global health community. "The criminals are winning," commented one official from the U.S. Department of Commerce.

Disorganized and underdeveloped law enforcement, together with relatively light conviction penalties, makes counterfeiting an attractive and highly lucrative business for entrepreneurs and organized criminals alike. "We have seen those who have previously trafficked in narcotics and firearms turn to counterfeiting medicines because they can earn more money and face much lighter penalties even if caught and convicted," said John P. Clark, Vice President and Chief Security Officer at Pfizer Inc., in a recent interview. "Advances in technology have made it increasingly tough to tell the difference between a counterfeit and an authentic medicine without a full chemical analysis. What was once seen as a problem limited to 'lifestyle' medicines is now recognized as a threat from which no therapeutic area is immune."[18]

Regulators around the world are issuing new requirements aimed at stemming this flood of counterfeit and falsified LSH products. These rules place new and significant burdens for security and data collection on all entities throughout the supply chain.

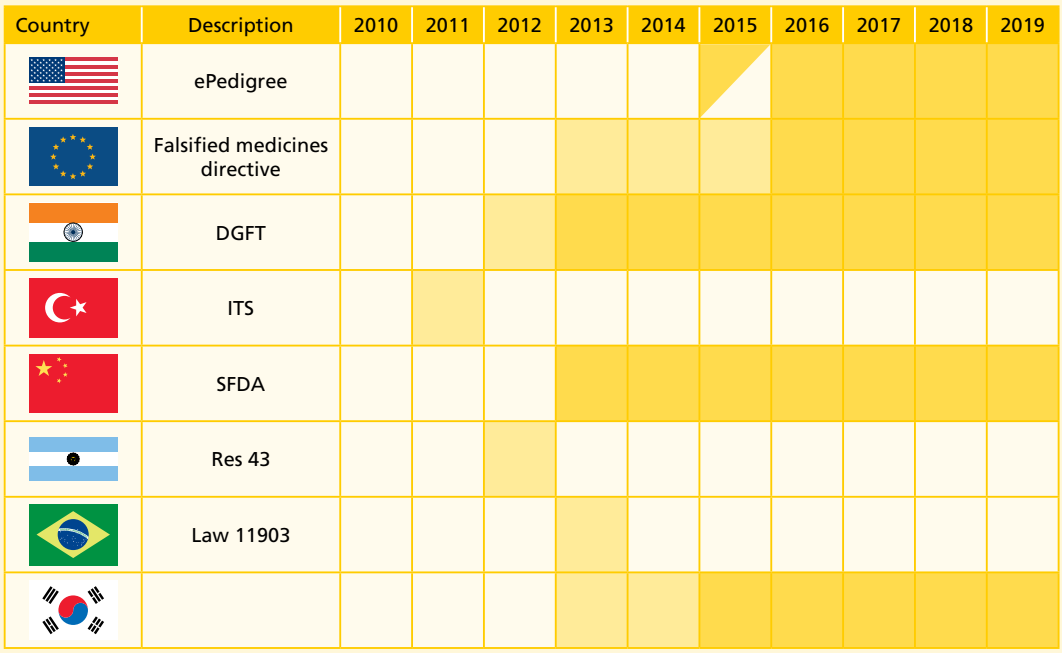
New legislation in the European Union introduces tougher rules to institute harmonized, pan-European measures to ensure that medicines are safe and that the trade in medicines is rigorously controlled.

In the United States, for example, the 2012 Food and Drug Administration (FDA) Safety and Innovation Act (FDASIA), the 2010 Patient Protection and Affordable Care Act, the FDA's proposed Unique Device Identification (UDI) rule, as well as product serialization and e-pedigree requirements, all carry requirements for new levels of inventory management, authentication and track and trace capabilities across supply chains. Pharmaceutical e-pedigree and serialization rules track the provenance of medicines and their components/ingredients. These regulations are issued at the state level, with California, Florida and Maryland leading the way.

The California law, which will be phased in from 2015, appears to be setting the standard for other U.S. states. It requires e-pedigree systems for prescription drugs that provide an electronic record of each transaction which results in a change of ownership of a given drug; from sale by a manufacturer, through acquisition and sale by every party in the sales channel until final sale to a pharmacy or dispensing agent. Serialization requires

[18] Jennifer Wall, Counterfeit Medicines: Q&A with Pfizer's Chief Security Officer, http://www.phrma.org/counterfeit-medicines-qa-pfizer-chief-security-officer#sthash.aU1Vkp5w.dpuf, May 21, 2012.

Figure 4: Timetable for global e-Pedigree and serialization initiatives



Timetable for global serialization initiatives. 'Level of aggregation' refers to how much of the supply chain is engaged (manufacturers, wholesalers, others). Countries include: United States, European Union, India, Turkey, China, Argentina, Brazil and South Korea. Credit: Systech.[19]

every product to be identified by a unique serial number in addition to the origin, shelf life and batch number. This allows the product's entire lifecycle to be traced from production, through distribution and finally to dispensing to patients.

New legislation in the European Union introduces tougher rules to institute harmonized, pan-European measures to ensure that medicines are safe and that the trade in medicines is rigorously controlled. Implementation will be phased in over the next five years. The EU approach focuses on authentication at the dispensary, made possible through a serialization database protocol. Other countries are following a similar regulatory path – with Turkey being a first mover in this area (Figure 4).

Many countries are also implementing requirements for medical devices – in the form of requiring a unique device identifier. In the case of the U.S. requirements, the intent is to improve the ability to capture medical device adverse event reports, as well as device performance data. This serves two purposes: it enables regulatory authorities to identify product problems more quickly, better target recalls and improve patient safety; and, it facilitates product performance tracking. The latter is increasingly important to governments and healthcare payers.

To comply with such regulations, the LSH industry, and all parties in the supply chain, must adopt rigorous serialization protocols and track products through the supply chain, normally by applying a unique identifier at the individual product unit rather than at lot level. This significantly increases the burden for scanning and tracking product, maintaining and sharing collected data, and protecting product integrity and the chain of custody throughout the entire supply chain.

[19] Nicholas Basta, Serialization and traceability inches closer to reality, http://pharmaceuticalcommerce.com/business_finance?articleid=26845, April 30, 2013.

Part 2: Building the new LSH supply chain

"The auto industry is accustomed to making cars around the world," observes Jonathan Blamey, Vice President, Global Product & Account Leader, DHL Supply Chain. "It is used to operating long supply chains, is accustomed to outsourcing and has integrated outsourcing partners into the supply chain quite thoroughly. The auto industry understands complexity, and has the systems, processes, partners and people in place to manage it."

Not so with the LSH industry.

From a supply chain development perspective, the global LSH industry is less mature when compared to the supply chain practices found in the consumer, retail or automotive sectors – primarily because the economics of the latter sectors, with their super thin margins, have forced an extreme focus on lean processes, efficiency and cost reduction. The good news is that, for the LSH industry, there is considerable opportunity for cross sector learning.

Historically in LSH sourcing and production, for instance, pharmaceuticals were traditionally made in "safe" places by the drug companies themselves – with little outsourced production. Now, medicines are made by third parties all over the world – suddenly creating greatly extended, complex supply chains.

On the outbound/demand side, growth is coming from emerging markets, so demand points can be anywhere. Additionally, more care is being delivered in the home to reduce overall cost and improve patient experience, in

particular for chronic conditions, further fragmenting the last mile of the LSH supply chain. Both trends inject complex new requirements into the channel.

While service has always been a high priority for the LSH supply chain – making sure the drugs and devices were available in ample quantities at the point of need – efficiency has not been a priority. There's a simple reason for this. The industry's average logistics cost as a percentage of sales was traditionally very low – in the order of 1.5 percent, according to a report from Accenture.[20]

It is only during the last three to four years, thanks to the challenges described in Part 1 of this paper, that LSH companies have begun to feel cost pressures and pursue greater efficiency, combined with the resiliency to respond to security, market demands and conditions. "There is tremendous opportunity – and a pressing need – to develop a new LSH supply chain that is fit for purpose in this new environment," acknowledges one pharmaceutical company supply chain executive.

"But unlike consumer goods or retail, you don't just switch on a pharmaceutical operation overnight," Blamey notes. "You have to configure the business for each market, each government system and each healthcare delivery system. Add manufacturing constraints, compliance, temperature control and other factors, and you get a highly complex supply chain."

The medical device segment of the LSH industry faces similar challenges. The device/implant supply chain calls for adequately planned inventories with the means to reach highly distributed locations with fast and reliable delivery. As the director of logistics for one medical device manufacturer comments, "In such a distributed environment, how can we maximize velocity, minimize inventory – and not miss surgeries?"

Historically in LSH sourcing and production, for instance, pharmaceuticals were traditionally made in "safe" places by the drug companies themselves – with little outsourced production. Now, medicines are made by third parties all over the world – suddenly creating greatly extended, complex supply chains.

Amplifying on the missed surgery theme, another supply chain director observes, "One of our greatest challenges is to make sure we have the right product in the right quantity at the right location, at the right time. Our surgical "kits" – everything the surgeon needs to perform the surgery – range in value from $30,000 to $70,000."

"Depending on the surgical procedure – whether it is a knee or a hip replacement – the total number of kit components varies from 150 to 400 items," the director goes on to say. The instruments in the kits are not universal, meaning the surgeon cannot substitute components from different OEMs because most of the components are uniquely engineered to support that specific implant.

"If our kit is not there when the surgeon goes to perform the surgery – he or she will use a product from a different OEM," the supply chain director continues. "So we lose the entire sale. That can easily add up to millions of dollars in lost opportunity in just a few weeks. Being able to manage our inventory better can directly increase our revenue in a very big way."

Nevertheless, certain best practices are emerging in the new global LSH supply chain. These practices are designed to address the issues of cost, service, geographical expansion, security, product integrity and chain of custody – and do so with greater agility.

[20] Accenture Life Sciences, How Excellence in Logistics Can Change the Fortunes of Pharmaceutical and Medical Device Companies, 2013, p. 2.

The control tower approach

At present, as a study from PwC points out, there are three distinct supply chains: designing, manufacturing and distributing pharmaceuticals; designing, manufacturing and distributing medical devices; and providing healthcare services (including laboratory work and pathology). From a macro perspective, integrating these supply chains so that all the upstream and downstream partners can see the full picture would enable them to plan ahead more accurately and manage demand more cost-effectively.[21]

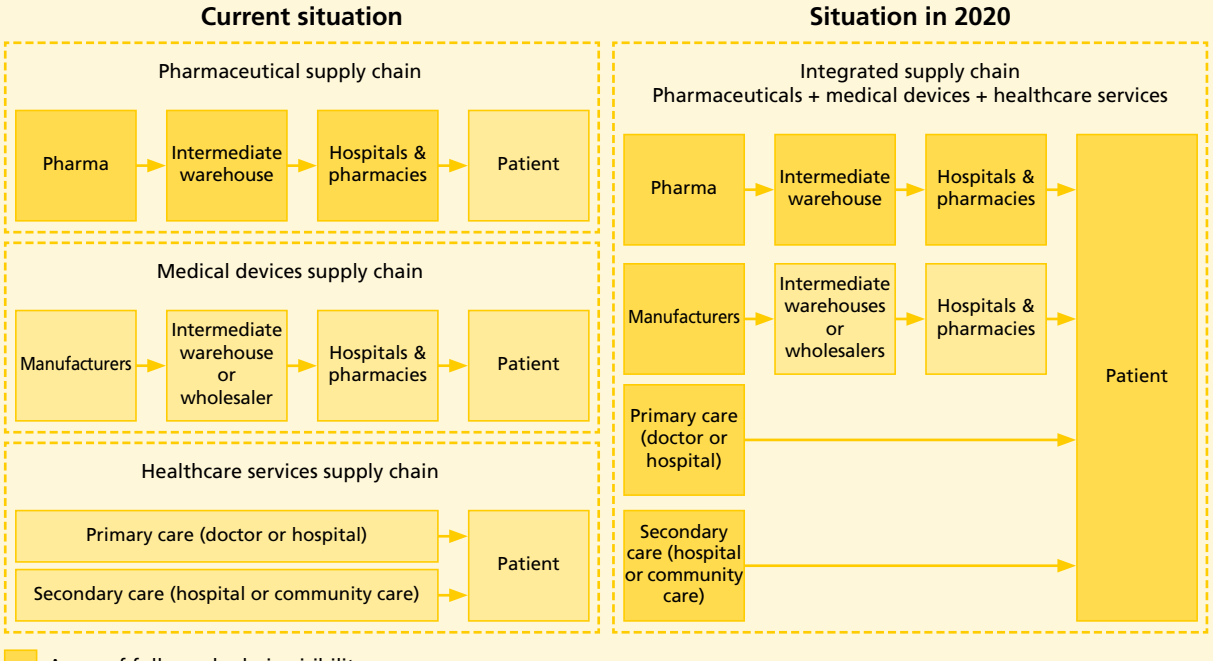
PwC predicts that such a model will emerge by 2020. Whether the LSH sector can meet that date remains to be seen. In terms of the supply chain, however, such a collaborative model already exists in industries like automotive and technology – and it could be customized to LSH with significant benefits. The model, called the supply chain control tower or lead logistics provider, is executed by some third party logistics companies.

Exactly what is a supply chain control tower? "Picture a room with computer consoles and overhead displays. Instead of air traffic controllers, you have a dedicated staff of supply chain experts monitoring those screens, which allow them to track freight movements and stay on top of any relevant developments. That visibility results in rapid notification of disruptions, allowing companies to take corrective action. Say an earthquake strikes a supplier in Japan. The supply chain manager can respond to the event, increasing the company's order of parts from a supplier in another part of the world."[22]

[21] PwC, Pharma 2020, 2011, p.14.
[22] James A. Cooke, Should You Build a Control Tower? DCVelocity, April 9, 2012.

Figure 5: The future LSH integrated supply chain

By 2020, the pharmaceuticals, medical devices and healthcare services supply chains will be fully integrated



Source: PwC, Pharma 2020, 2011.

At the heart of the control tower concept is real-time visibility across the extended supply chain – incorporating suppliers, manufacturing nodes, carriers and third party logistics service companies, and customers. A lead logistics provider (LLP) sits atop the control tower, using real-time visibility tools to constantly monitor and assess the condition and performance of the supply chain. Thanks to alerting systems, potential or real problems can be identified and addressed proactively – before they disrupt the supply chain.

Real-time visibility enables the supply chain to be orchestrated in a collaborative fashion, reducing risk from the unknown and thereby improving resiliency. Global best-in-class LLPs can provide what amounts to an on-the-ground sensor grid in their countries of operations, geared to monitoring supply chain conditions continuously. This capability is particularly important for LSH companies who are expanding their geographic footprint in new markets.

The control tower approach makes sense for life sciences companies.

The control tower model can be a highly effective way to manage the daily operations of a global supply chain, and, on a more strategic level, identify and manage risk and disruptions. Better visibility also reduces inventory in the channel. This is especially important in an environment where generics replace high margin products, and inventory buffering practices have reduced turnover to unsupportable levels. And supply chain network design, a hallmark of the control tower model, optimizes the network for both cost and service.

Expanding on this last point, Blamey observes, "In a typical retail/product environment, you'd see 20 to 30 days of stock on hand. In many pharmaceuticals supply chains, it's more like three to four months on hand. Medical devices are 200 to 300 days. These are very inventory-heavy supply chains, and as products become more expensive, and drugs are tailored to smaller and smaller populations, this high inventory model becomes unsustainable."

If the industry can improve the quality and flow of information and reduce uncertainty, among all the players in the supply chain, it can meet the twin challenges of controlling and reducing costs, while delivering required service levels. "This is not something we can accomplish alone," acknowledges the supply chain director for one global LSH company. "We need to bring all of our partners to the table, including our 3PLs, and all work together to streamline how we get product to the customer."

"The control tower approach makes sense for life sciences companies," Blamey explains, "as a means of addressing these complex issues while still ensuring continuity of supply."

Product security and compliance expertise

As new regulations for product security take effect, and more products in the channel require temperature control, LSH supply chains take on a far more demanding product stewardship role. This role requires significant investment in processes and systems designed to comply with regulations regarding both the physical product and the information attached to that product.

The shift to biologics, which have very specific temperature and handling requirements, creates a very broad set of challenges for supply chains, particularly in emerging markets. Notes one supply chain executive at a major pharmaceutical company, "Biologics are not only more costly/higher value, but they are also very sensitive to pressure and temperature which presents a whole set of challenges for supply chains."

The regulatory bodies are trying to keep up with the issue of protecting "perishable" LSH products as they traverse the global supply chain. Last year, for example, there were approximately 30 worldwide additions or changes made to "good distribution practices" (GDPs) as part of the management and regulation of pharmaceutical transportation and storage. GDPs exist in various forms, in numerous countries or regulatory jurisdictions, and their principles are in place in many contractual agreements between manufacturers and service providers.[23]

As security and compliance requirements increase, so too does risk. The consequences of failure can be dire. "It's not like with the auto industry, where if you don't make a car, you just lose a sale," notes one global pharmaceutical supply chain vice president. "In this business, if you lose a shipment of vaccines, people may die."

Precisely because of the growing complexity of caring for and handling LSH products, a growing number of LSH manufacturers are outsourcing their distribution operations to third party logistics service providers. Such providers must be able to provide specialized pharmaceutical and medical device grade facilities that meet specific quality and validation requirements. These facilities typically have:

- Refrigerated (+2 to +8°C) and controlled ambient areas (+15 to +25°C)
- Specialist storage zones (-20°C, -80°C, -150°C)
- Controlled drugs vaults
- 24 hour security and environmental monitoring
- Clean areas for assembly, kit building and labeling activities.

Protecting and certifying the integrity of the new biologics medicines, vaccines and therapies requires a significant investment in cold chain capabilities. This cold chain requires physical assets, procedures,

[23] J. Quinn, Emerging Markets Influence Changes in Global Pharma Distribution, Pharmaceutical Commerce, July 2012.

monitoring and reporting on a far greater level than the pharmaceutical supply chain of old. These do not come without a cost. UNICEF and the World Health Organization estimate the additional cost of cold chain logistics for vaccines, for example, to be between $1 and $20 per child depending on location. At the same time, the World Health Organization reports that about half of all vaccines are wasted due to temperature excursions as a result of poor cold chain control.

One hallmark of the new resilient LSH supply chain, therefore, is effective cold chain management. From a storage perspective, this means:

- Higher value of drugs stored
- Greater risk of stock loss due to temperature excursions (over and above traditional pilfering and damage)
- Greater requirement for electricity usage in a world where green pressures to reduce carbon are increasing
- Higher skill level of operational staff in handling these products
- Increased need for cold chain packaging and handling solutions
- Increased capital requirements – controlled temperature facilities are more expensive.

Similarly in transportation, this broadened need for temperature-managed transport carries several impacts:

- Increased cost of the transport fleet in terms of equipment, maintenance and fuel
- High degree of compliance risk to ensure temperature requirements are met at all times
- Increased impact on carbon footprint
- Additional complexity in a shared user environment to ensure that all products are maintained according to their requirements
- Potential risk for non-compliant suppliers, which puts product integrity at risk.

Shared services model

A natural extension of outsourcing to a third party logistics provider – reducing costs while building in capabilities – is for LSH companies to participate in a shared service distribution model. In this shared service model, multiple customers share the same physical platform and the same supply chain operational processes. The model is based on economies of scale – i.e. spreading the cost of a best practice LSH distribution operation across multiple companies.

In developing markets, where distribution channels are fragmented and lack transparency, this shared services model can provide significant benefits to LSH companies. In these markets, pharmaceutical and medical device manufacturers typically have customer overlap, meaning that multiple companies are shipping to the same group of customers. This means that across manufacturers, there is considerable duplication of supply chain assets, resources and costs – all geared toward serving the same customer cluster.

Manufacturers can reduce this redundancy by using a single logistics service provider to create a shared, multi-customer supply chain solution. This solution would manage the flow of products to and from the hospital or healthcare facility. The idea would be to cluster manufacturers in a single warehouse near the major point of consumption, and consolidate deliveries and services to that health facility/hospital. The multi-customer facilities could also be set up to handle home delivery and in-home services.

"Having six different deliveries to a hospital, going to six different wards, with four different highly trained drivers doesn't make a lot of sense," explains Scott Cubbler, President, Life Sciences and Healthcare, Americas, DHL Supply Chain. Instead, a third party logistics firm (3PL) could create a shared services hub, consolidate shipments, eliminate overlapping deliveries and provide full delivery service with fewer redundant assets.

In developing markets, where distribution channels are fragmented and lack transparency, this shared services model can provide significant benefits to LSH companies.

This kind of operation is similar to the just-in-time "milk run" delivery systems that feed automotive plant assembly lines. It is found in a small number of markets around the world at present, including the National Health Service in the United Kingdom. As proven in the automotive sector, such a system reduces supply chain costs for the manufacturers, and could greatly simplify the hospitals' receiving activities.

Sharing transportation can offer distribution synergies, among manufacturers shipping to the same end customer, by consolidating shipments of compatible products to achieve fewer half-empty delivery runs, less duplication and greater efficiency. The aggregation of cargo can enable new direct delivery routes that eliminate unnecessary hand-offs and shorten delivery cycles. Given the increasingly delicate nature of the products being handled, and the need to track every single movement and transfer, this kind of service easily supports more effective product management.

Toward adaptive execution

The constellation of challenges facing LSH companies today is unprecedented. The market is changing rapidly – with a focus on cost control, robust growth in emerging economies, profits under attack as blockbuster drugs come off patent protection and requirements for personalized medicines. Burgeoning demand is running up against the diminishing willingness or ability of government and private payers to fund those demands. The counterfeit drug trade is reaching epidemic proportions. A blizzard of new regulations is governing safety and security. In order to prosper in this new environment, LSH companies must adopt a more resilient, adaptive supply chain model.

This means working collectively with all business partners and service providers to craft supply chains for optimal end-to-end flexibility. The new LSH supply chains must be able to embrace the unpredictable – to anticipate and mitigate risk, manage globally extended operations with real-time visibility and facilitate truly adaptive execution.

E-PEDIGREE AND SERIALIZATION MODELS

Figures 6 and 7 illustrate the California and European approaches to pharmaceutical e-pedigree and serialization management. The key difference lies in the establishment of a centralized serialization reporting database in the UK model.

Figure 6: The California e-Pedigree approach

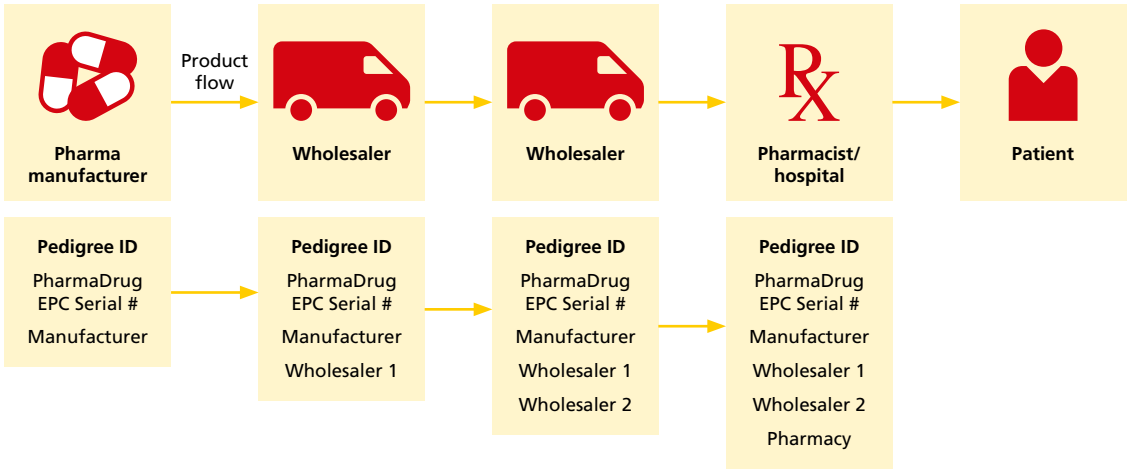
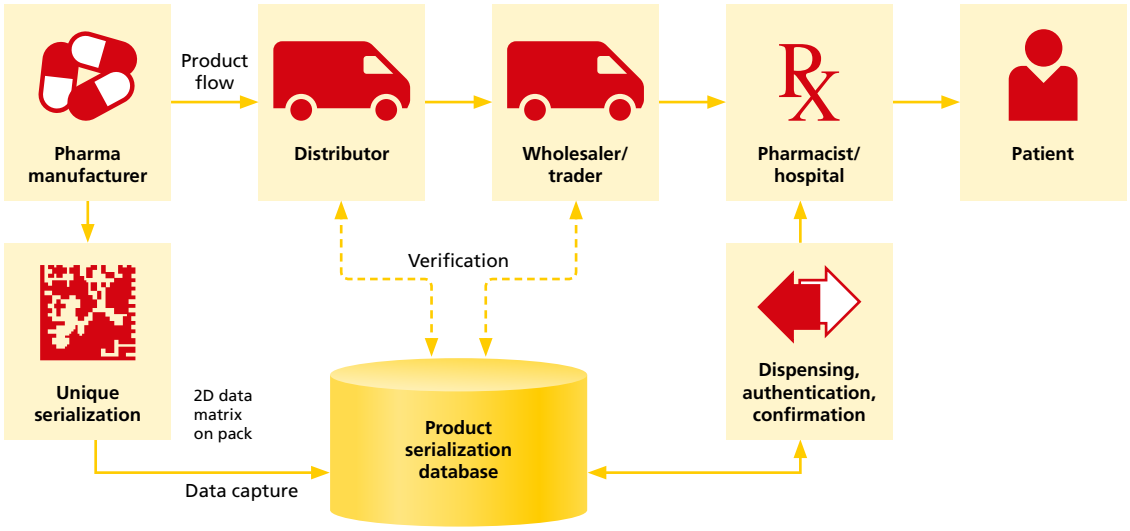


Figure 7: The European serialization and authentication approach



Source: Oracle Life Sciences. Combating Counterfeit Medicine: Enabling Mass Serialization and Pedigree Management in the Pharmaceutical Industry, August, 2010.

About the author

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