The golden age of innovation is beginning

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Drug Delivery and Packaging Report 2019

Europe to become major hotbed of drug delivery innovation driven by rising biologics capacity and diversification of market entrants.
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The golden age of innovation is beginning

Introduction

The last two years have been some of the most remarkable years in pharmaceutical history. There were 46 FDA approvals in 2017, and this year we have received over 50 approvals. We might now be entering a golden age of innovation for pharmaceutical R&D, but what is most encouraging is that this new era of increased productivity is translating into drug delivery devices and packaging as well. In fact, many of the experts that we spoke with ahead of Pharmapack Europe 2019 believe that this new age of innovation is a golden opportunity for drug delivery and device manufacturers to bring new technologies to patients. Perhaps more significantly, the FDA is actively encouraging manufacturers to innovate, which should enable more of these new technologies make it to market. With the year coming to a close and Pharmapack opening early in February 2019, we have produced a short report containing survey data and insights from our Pharmapack experts, looking ahead at the next few years of the new drug pipeline and how an increasingly creative technology environment is impacting patients. This report in particular will focus on the implications for the European market, including the inaugural release of a European drug delivery innovation ranking – the data from which was extrapolated from the recent CPhI Annual Report 2018.

Experts that provided input:
Special thanks to the following experts who supplied their analysis on the changes and challenges in the market over the next 1-3 years:
- Fiona Barry, Associate Editor, PharmSource, a GlobalData product
- Andy Fry, Founder of Team Consulting
- John Burke, Senior Consultant at Team Consulting
- Gerallt Williams, Director Scientific Affairs, Prescription Division, Aptar Pharma
- David Braun, Global Head of Medical Device Business Solution at Merck Group
Background

There are a number of factors driving significant growth in the packaging and drug delivery sectors, notably a diversification of innovators, with an increasing number of small and medium sized companies entering the market. Personalized medicine, genomics, the internet of medical things (IoMT) and connected devices, as well as the continued expansion of the biological pipeline are driving patient focused developments and innovations. At the same time and supported by these trends, there has been a notable return of investment to the R&D industry by VCs (venture capitalists) and pharma itself, both of which have been looking for, and investing in, the next wave of emerging technologies. However, as highlighted in the recent Mordor Intelligence Report, there are also a number of market restraints slowing overall growth rates, including rapid rises in product recalls and challenges in nanomedicine based drug delivery. The final major change occurring across pharma is the continued rise of outsourcing in the supply chain, which allows pharma and biotech companies to concentrate on their core strengths in research and development and marketing drugs. The impact of this for pharmaceutical drug delivery and packaging solutions is that we are seeing the rise in pharmaceutical packaging companies, particularly in Europe, and increasingly, drug delivery innovation is being developed collaboration with specialist firms. In Europe, contract packaging companies are set to grow particularly quickly with PCI Pharma, Almac, IDT Biologika, Recipharm, Vetter and Sharp Packaging Solutions amongst a host of players leading a surge in demand.

“Changes in drug therapies are forcing parenteral delivery devices into new challenges. These include the push from regulatory bodies for paediatric approved drugs, the demand for ever-increasing volumes for hand-held and wearable injectors, the demand for more self-administration, and the challenges facing new therapies getting to market.”

– John Burke, Senior Consultant at Team Consulting

What Do the Analysts Say?

Analysis of the global packaging and drug delivery market, as well as the associated forecasting of the future growth potential depends greatly on the exact criteria of market conditions used. However, the majority of reports we reviewed show substantial growth in the early teen range over the next five years for both contract packaging and drug devices – with the European injectables market showing particular promise. In fact, globally by 2022, it is estimated that the injectable drug delivery market will be worth a staggering $624.5 billion with global companies, Baxter International (U.S.), Pfizer (U.S.), Gerresheimer AG (Germany), Becton, Dickinson and Company (U.S.), Schott AG (Germany), Eli Lilly and Company (U.S.), and Terumo Corporation (Japan), driving forward innovations and market development. In terms of product classes, biologics continues to bring newer and more complex drug delivery to the market, with chronic diseases like diabetes, rheumatoid arthritis and cancer increasing the demand for injectable delivery. Another key market trend has been innovation that has helped the patient...
self-administer the drugs – such as pre-filled, needle free delivery – and smart applications that help the patients monitor dosing and time of delivery. It is a particularly significant trend, as healthcare prices continue to rise globally, and delivery mechanisms that remove the need for supervision of a healthcare professional, help to reduce the overall cost burden in public and private health economies. Andy Fry, Founder of Team Consulting, commented, “The balance between sales of ‘conventional’ and ‘biologic’ drugs have shifted progressively over the past few years, with biologics going from 32% of the top 100 drug products in 2010 to close to 50% in 2018 (Evaluate Pharma World Review 2018). Given that virtually all biologics are parenterally delivered, the majority of these self-administered, the strong demand for wearable delivery devices, autoinjectors, and pens, as well as prefilled syringes and dual chamber products, is expected to continue in 2019.”

New delivery options are also driving growth. For example, Genetech recently had their single dose, prefilled auto injector formulation of Actemra approved by the FDA to treat severe rheumatoid arthritis. This new dosage form not only gives patients additional administration options, but it also extends patent protection on an existing approved drug, and combination products like this will help protect against future generic encroachment. New delivery options are also driving growth. For example, Genetech recently had their single dose, prefilled auto injector formulation of Actemra approved by the FDA to treat severe rheumatoid arthritis. This new dosage form not only gives patients additional administration options, but it also extends patent protection on an existing approved drug, and combination products like this will help protect against future generic encroachment. New delivery options are also driving growth. For example, Genetech recently had their single dose, prefilled auto injector formulation of Actemra approved by the FDA to treat severe rheumatoid arthritis. This new dosage form not only gives patients additional administration options, but it also extends patent protection on an existing approved drug, and combination products like this will help protect against future generic encroachment.

On the European side, the injectables market will reach $207.3 Billion by 2020, nearly doubling from $114.7 Billion in 2015, showing a compound growth rate of nearly 13% over five years. The population in Europe is suffering from a similar disease burden as the US, and is increasingly switching to advance drug delivery methods. For example, with diabetes patients switching to needle free, painless injectable forms. These again are often disposable products that do not require any specialist skills for administration.

Oncology, particularly with the rise of combination therapies, is also stimulating innovation with injectables that can deliver two actives at once being increasingly developed. The unifying trend across all drug delivery devices is the global preference to improve the patient’s user ability, compliance and experience. For example, smart dose injectors, multi dose delivery injectable caps and smart, dry powder inhalers are just a small part of recent approaches that have been designed to control and monitor appropriate use. Similarly, implants and transferred patches are another growing area, whereby the drug developer can more closely control dosing and delivery of drugs, particularly for drugs that require sustained and controlled release. Switzerland remains another key innovation market, led by the large number of big pharma companies based in the country, but also by specialist drug delivery innovation companies such as SHL Group and a number of key drug delivery research officers and world class university research centers.

“What we will see in Europe in 2019 is a continued rollout of drugs coming to market using auto injector technology. The ease of use and patient experience will become fundamental to their design.”

– David Braun, Global Head of Medical Device Business Solution at Merck Group

In fact, the European market for new drug delivery systems is already the second largest in the world, according to Mordor Intelligence, sharing 30% of the market. The CPhI Annual Report 2018 shows a concurrent trend with biologics manufacturing capacity, which we expect to overtake the United States in the next five years. This analysis, conducted by Dawn Ecker of BioProcess Technology Consultants, was completed by looking at predicted biological expansions and new investments. This is of particular interest to delivery device manufacturers because a large proportion of biologicals in the next few years will increasingly come with unique delivery mechanisms. This would suggest that if greater manufacturing is brought into the European market, there is also a parallel opportunity for substantial growth in drug delivery and packaging within Europe. Interestingly,
perceptions of quality of innovation of drug delivery and devices within Europe remains high – behind only the U.S. and Japan. David Braun agrees that “it has the potential to boost the European Industry,” which could see a gradual shift towards Europe as we have seen in biologics in the last 10 years. However, Braun remains unsure about how this may play out in the near future, as he believes that “with today’s globalization, things could remain as is. This industry has a hard time to change partners or suppliers unless there is a very good reason for that.”

European Drug Delivery Ranking

Advanced Therapies

“Within Europe, a disproportionate number of ATMPs (advanced therapy medicinal products) are manufactured in the UK, according to our report (PharmSource: Cell Therapy Market Opportunity for CMOs – 2018 Edition, June 2018). Whether this trend will continue will depend on how Brexit is resolved. In a poll of GlobalData Healthcare clients, the majority of respondents predict a negative result of Brexit for the UK healthcare industry – and the number of respondents predicting a negative result has dramatically increased between the second and third quarter of this year (Brexit and the Healthcare Industry – Implications for Pharma, Q3 2018). If this commonly held opinion is correct, we would predict the UK’s dominant position as an ATMP manufacturer to be lost to Germany, the Netherlands, and Belgium.”
– Fiona Barry, Associate Editor, PharmSource, a GlobalData product.

The European data analysis from the CPhI Annual Report 2018 contains insight from 350 global pharma executives has been compiled together by Pharmapack Europe, creating the first European ranking of innovation across drug delivery devices. Ahead of the European-focused Pharmapack event, we have excluded results from outside of Europe to create a European ranking table. In the original research, the United States, Germany and Japan retained for the second year running the top spots in terms of perception of ‘API’, ‘final product’, and ‘biologics’ manufacturing. This research shows that mirroring the findings in both solid dose and biologics manufacturing, Germany remains the preeminent source of innovation within Europe. Interestingly, for drug delivery innovation France scored only narrowly behind Germany – perhaps due to a number of leading device manufacturers being based there, notably Nemera, BioCorp and Aptar. Third within Europe was Switzerland, followed closely by the United Kingdom. A second tier of nations, in Spain and Italy finished the bottom of the primary European markets.

“No real surprises here, the rankings are probably related to government support of innovation/R&D and the facilitation and levels of support offered to start-up/incubator companies in each country.”
– Gerallt Williams, Director Scientific Affairs, Prescription Division, Aptar Pharma

Unfortunately, due to the methodology of the research, there was no data available for Sweden, the Netherlands or Ireland, but one might have expected these nations to score highly, perhaps between the tier one and tier two nations. For example, the CPhI Annual Report does contain data on the rankings of biological manufacturers in Europe, and both Sweden and Ireland scored particularly strongly due to the presence of several international contract manufactures based in their countries. We would anticipate that innovative drug delivery startups would begin to appear around these notable manufacturing hubs over the next few years.
“We would suggest that in terms of worldwide rankings it would be interesting to include Canada because of the number of facilities that do contract dose manufacturing in that country. In European rankings, it would be beneficial to include Sweden in the future because of the number of facilities in the country that perform contract dose manufacturing.”

– Fiona Barry Associate Editor, PharmSource, a GlobalData product
Packaging Innovation and Regulation

The packaging sector has also seen a great deal of transformation innovation over the past few years, notably as the industry focuses on personalized approaches, dosage forms and the localized production of customized medicines. In the future, we are likely to see newer medications with labeling and packaging manufacturing produced in smaller batches with short lead times, and closer to the patient. Another recent development should be the implementation of unique server name identification (SNI), serialization and track and trace solutions designed to reduce to counterfeit medicine and increase accountability.

David Braun believes that in the next year, we are likely to see “an increased number of connected devices and health solutions reaching the market”. But in terms of packaging, he thinks that “smart packaging is going to provide a real added value for the patient and a number of advantages for companies implementing it.”

In fact, the EU’s Falsified Medicines Directive comes into effect February (9th) 2019, resulting in mandatory serialization across the EU. The United States is also in the process of implementing the Drug Supply Chain Security Act (DSCSA), with full completion being set for 2023. However, while there are multiple implications for contract manufacturers and license holders, these newer tracking technologies should aid the introduction of more innovative packaging and delivery devices and solutions. All of this new legislation is meant to create smarter, safer medicine and to protect the public against the selling of falsified medicine.

Fiona Barry however warns that her research shows that despite years of buildup, there is still a significant number of smaller companies unprepared for the imminent deadlines and changes within the EU. Barry, commented “in our November monthly report (Bio/Pharmaceutical Outsourcing Report), we heard from a US packaging expert who said he has seen ‘many smaller clients in panic mode’, adding ‘I don’t think there is enough human capacity to ramp-up these late requests’. An EU expert predicted that this slippage will continue until regulators start penalizing the companies that are late. ‘We are still in limited supply of those that are ready, an EU Contract Packaging Organization told us. So serialization will just be the start of many issues relating to data integrity as pharma packaging becomes more sophisticated and traceable.”

Increased environmental focus?

Mirroring the pharma industry’s desire to reduce its environmental footprint in manufacturing processes, both packaging and license holders are likely to come under pressure to create biodegradable and recyclable options – especially in products where plastic solutions are in heavy use. “Undoubtedly, sustainability will have to become a much more important influence over the next few years” added Gerallt Williams. The long-term implementation of all of these concurrent trends is that packaging manufacturers, distributors and license holders are going to need to have far more adaptable packaging solutions, with a wider array of options to meet a diverse type of product entering the market. The future is unlikely to be dominated by large scale production of generic, high volume, low cost glass bottles, but more personalized delivery vehicles whether for generic or patented products.

Transforming Drug Delivery Innovation into Commercial Products

Over the next few years, it is likely that 3D printing will increasingly have a role to play in packaging, particularly as scales are smaller and dosage forms move closer to patients. One of the other biggest shifts in the industry over the last 10 years has been the diversification of sources of innovation – particularly as mature technologies from other industries now look to bring new benefits to drug delivery devices. This has led to a large shift in the industry where traditionally, the main source of innovation has come from big pharma and multi-national drug delivery device firms.
However, as emphasized by Pharmapack’s own Innovation Gallery, what we are now seeing is a large number of smaller and highly agile firms developing more specialized and consumer friendly technologies. In particular, innovations are focused on patient friendly solutions that either improve the experience, dose-controlled monitoring or compliance. When looked at holistically, what’s clear is that the industry is collectively trying to move the delivery of drugs closer to the patient – potentially reducing the overall burden of healthcare providers. For example, pre-formulated, pre-filled syringes, which reduce the need for dosing. Taken a step further, auto injectors can also allow a patient to conduct the delivery in isolation at home, with potentially a smart tool such as an app that notes the time of administration and simultaneously informs the healthcare provider. In fact, we predict that over the next one to three years, the rate of innovation with drastically increase as an even wider array of new companies get funding to produce exploratory clinical products.

“Smart devices and connectivity remain hot topics. The technology is rapidly becoming more established, more available, more compact and cheaper; a common pattern with electronics and IOT related technology in other markets.”

added Andy Fry

The challenge, of course, in such a heavily regulated space will be having the size and experience to transfer the promising innovations through the pipeline and into commercial solutions. The net results of this is likely to be an increase in licensing deals between small and larger firms as well as numerous acquisitions and co-development deals.

“The big challenge is and will remain in scaling up from prototyping into an approved product going through clinical trial, and the same is most definitely true of bringing the product to full commercialization.”

– David Braun, Merck Group

Barry, summarizing her perspectives collectively on what the recent spate of innovations we have seen and the rising number of FDA approval means for contract manufacturing sector added: “Our trend report (PharmSource: Contract Dose Manufacturing Industry by the Numbers: Composition, Size, Market Share and Outlook - 2018 Edition, August 2018) shows the complexity of new APIs is increasing, and so in turn, are the issues around delivering these complex molecules. We’re going to see these trends affect drug delivery revenue growth, as many CMOs will not have the capability to provide the new technological capabilities required. So finished dose CMOs will have to improve their formulation and drug delivery technologies to compete for clients, with products that are increasingly complex and have poor solubility.”

Conclusion

When looked at holistically, the combined trends of the drug delivery and packaging sector over the next few years demonstrate a clear desire from regulators, developers and patients to improve the overall patient experience and centralize treatment options around the patient. In Europe, this aspiration coupled with a growth in biologics manufacturing and a new age of innovation is redefining the art of the possible and reimagining delivery options and adherence options. In fact, we would predict that a number of new innovation hubs with a more diverse mixture of smaller, highly agile companies will become established in the next few years across France, the UK, Switzerland and Germany. These countries in particular have an established center of innovative companies, coupled with a large and growing biologics industry that is driving many of the innovative drug delivery options.

Such is the rate of innovation in Europe, the injectables market should double in size in just over five years, reaching some €200million by 2020. Auto-injectors and
needle free injectors are likely to grow particularly quickly. Connected technology and the internet of medical things are also bringing newer market entrants into the European drug delivery market and our experts forecast this will bring in established technologies from other areas that will have profound and transformative implications for patients. The only potential ‘brake’ to this growth and acceleration is a reluctance by global pharma to change partners and work with newer providers, as well as still some degree of uncertainty as to how many of these more innovative drug delivery devices will be successfully scaled-up and commercialized, whilst still meeting stringent regulatory requirements. It’s one thing to demonstrate proof of concept, but a good deal more complex to deliver an approved device. As a result, what we will likely see is the larger drug delivery manufacturers and pharma companies scouring these new innovation hubs for licensing partners and acquisitions. Ultimately, these new combinations of small and large companies should help accelerate and enable these new, ground breaking technologies to reach the patient without becoming slowed by scale-up challenges or regulatory approvals. In fact, it is likely that VC funding – that is currently in a relatively buoyant period – will be required to support the early stages of innovation before pharma and larger companies take over the later stages of development. Other potential factors slowing innovation, particularly in the United Kingdom, will be the long-term implications of any trade deals negotiated between the United Kingdom and the EU. For instance, there is a good deal of uncertainty around the advanced therapies market – which the UK is currently the European leader in – and how this will be affected and/or if manufacturing will be moved to other European centers.

Serialization, which is now being implemented across the EU, could also be the beginning of a new age of connected devices healthcare solutions reaching the market. With technologies that track not only where a pharmaceutical product is in the supply chain, but also, at what date and time the patient administered the drug, resulting in improved compliance, clinical trial data and reduced physician intervention. However, many analysts forewarn that despite a number of years of preparation, a large number of smaller companies across the EU remain inadequately prepared for full implementation of serialization regulations and if a crisis is to be averted, they will need to rely on the ‘good grace and flexibility of the regulator’.

What is most exciting about all of these changes, when looked at collectively, is that there is an increasing diversification of the types of companies, types of professionals, and collaborations in the industry driving innovation forward. Other industries have clearly shown that when an open-access approach to new technologies is taken, transformational changes are often quick to follow and in five years’ time, it is likely that the drivers for change will see a much larger and diversified drug delivery and packaging innovation hub in Europe. There will be a far larger injectables, biologicals and connected devices market, with a number of innovation hubs established, not only in the major advanced European pharma markets, but also potentially in newer and smaller centers such as Ireland, Sweden, the Netherlands, and Belgium. The last two years have been a golden period for FDA approvals, however, the coming 5-years are expected to be a golden period of innovation for drug delivery and packaging devices across Europe.
References
