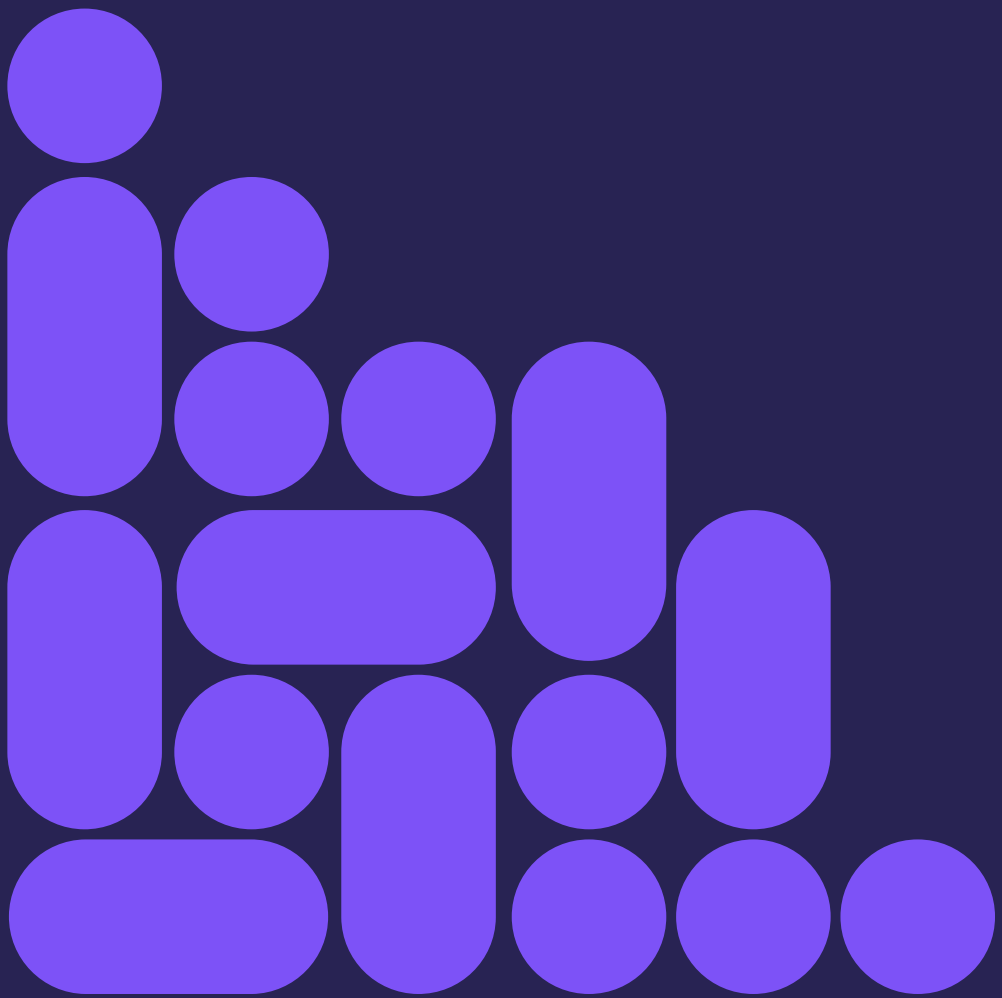
Pharmapack Survey and Annual Report 2023

Survey suggests global innovation to recover much more quickly than expected in 2023

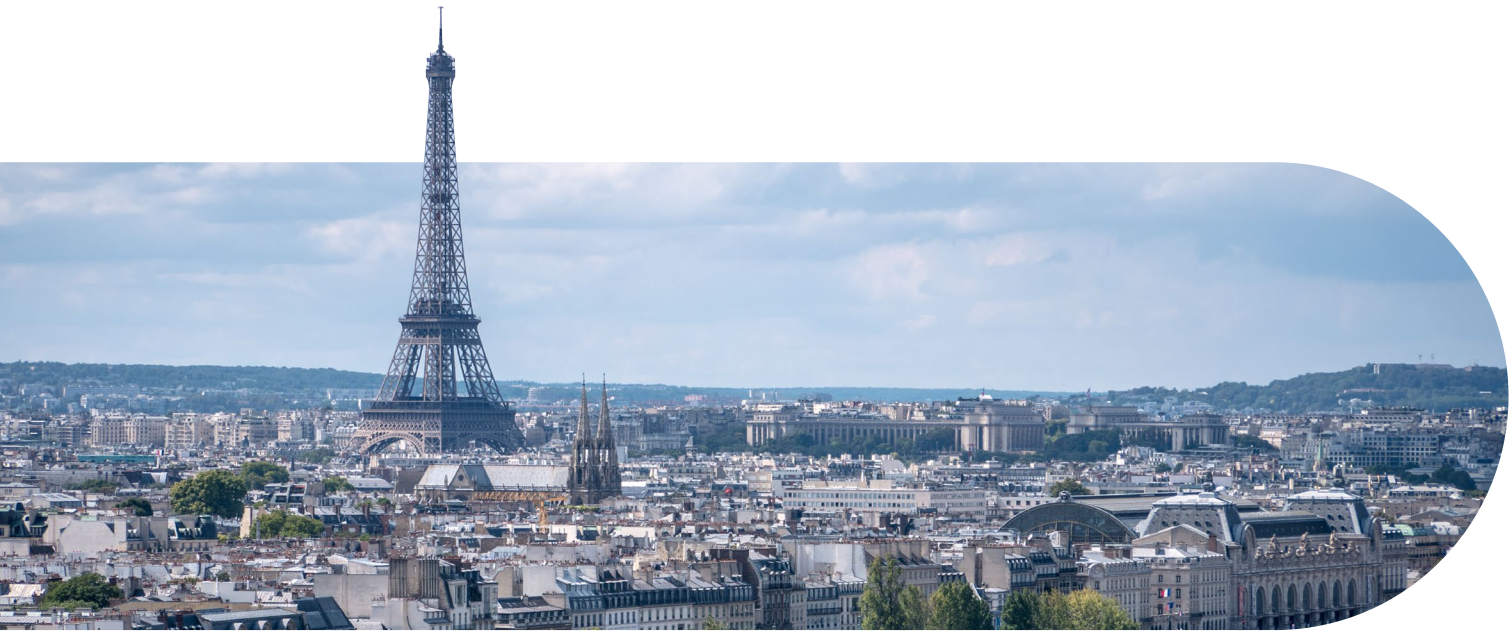
PHARMAPACK
By CPHI



Contents

Part 1

USA, Germany and UK pull clear as tier one nations in the Pharmapack Drug Delivery Innovation Index



Introduction

As the world moves into a post COVID period, the Pharmapack 2023 Market Survey's key metric, the Pharmapack Drug Delivery Innovation Index (scored out of ten), has seen a rapid rebound ahead of Pharmapack Europe 2023. The Index collateralises the scores of the main pharma innovation nations to produce an overall score. After a brief fall in 2022 to a score of 6.5 (results from May 2022) – the first decline since its inception in 2018 – the index has surged to a record score of 7.4. This sudden recovery in scores over a little more than eight months bodes extremely well for device and packaging manufacturers in the year ahead, suggesting a strong global recovery in industry outlook and confidence.

It did seem paradoxical in May that the innovation horizon should be seen as narrowing at a time when pharma, in general, and the drug delivery sector had played such a central role – through innovation in the face of unprecedented challenges – in global public health efforts. But, given COVID's unparalleled supply side impact globally, it's inevitable that we saw some reduction in confidence, the surprise is that this has reversed so dramatically and so quickly. It indicates that industry executives now feel many of the pressures of the last 12-months are easing – i.e. stabilising gas prices in Europe, inflation moving back towards historical norms, and a loosening of parked capital in private equity firms and Venture Capitalists [as reported in November 2022's CPHI Annual Report]. Moreover, market fundamentals remain very healthy with analysts projecting a global market value of $394 billion by 2027, a solid compound annual growth rate (CAGR) of 7.40% on its 2021 rating of $258 billion.[1]

An added dimension is presented by opportunities to bring COVID-related learnings and developments to bear on development timelines and opportunities. For example, difficulties in accessing healthcare face-to-face during the pandemic gives further momentum to the ongoing trends in patient-centric delivery. Self-administration and homecare will combine with increasingly connected delivery solutions to lessen burdens on healthcare systems while improving the patient experience. Connected devices are not new and still underutilised in most markets, but the increased adoption of healthcare-related apps and online services during the pandemic suggests there's an increased openness among patients to adopt new tech. There's also renewed emphasis on innovation moving away from the COVID-driven focus on injectables toward mechanisms like nasal delivery, and next generation approaches to mRNA delivery.

[1] *https://www.globenewswire.com/news-release/2022/04/22/2427173/0/en/Drug-Delivery-Devices-Market-Growth-Trends-COVID-19-Impact-and-Forecasts-2022-2027.html*

> *"This represents a significant challenge for device and packaging manufacturers and is the best opportunity to introduce innovative features in novel devices and packaging. There are some positive growth opportunities that have materialised, namely a focus on homecare services, of which self-administered medicines plays a crucial part."*

Aurelio Arias
Engagement Manager, EMEA Thought Leadership at IQVIA

At the same time, the sustainability question continues to weigh heavily in this year's report, with many innovation opportunities come with environmental costs, in particular, connected devices.

This report is a deep dive into these observations, evaluating the changing perception of innovation in the drug delivery device sector, as well as exploring how far along each country is in terms of achieving optimal sustainability of pharma devices and medicines. Looking further ahead, the findings will provide insights into what drug delivery devices will see the biggest areas of innovation over the next 5 years.

*Pharmapack Europe is the largest drug delivery and packaging event in Europe and welcomes more than **300 exhibitors** from **75 countries**. The event features an International Meetings Programme (business matching), a full 2-day Conference, Learning Lab presentations, eponymous Awards, as well as areas for new innovations in the Start-up Hub, Innovation Gallery and Tours. In total, the event will play host to some **5500 attendees** and more than 50 dedicated content sessions.*

Methodology

The results provide an inside track on the overall strength of the industry while also drilling down to provide insights on key areas and topical questions. With Executives from around the globe – including all major pharmaceutical markets – contributing their specialist perspectives, the Pharmapack Survey is the go-to resource on the drug delivery and packaging market in 2023. The most recent survey results were collated in early 2023, with Canada and Sweden removed the Index, due to limited responses, with early survey data undertaken in May 2022.

Innovation entering the post-COVID world

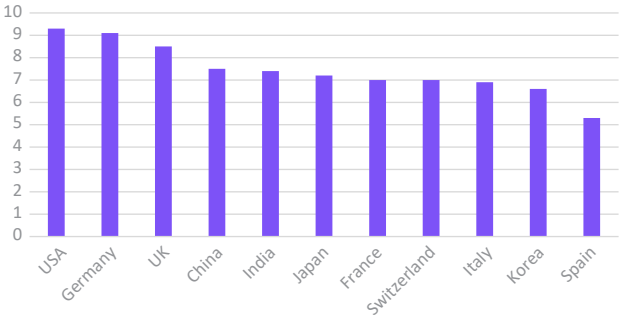
The report's key metric is the 'Drug Delivery Innovation Index'. Scored out of ten, this provides a measure of the strength of innovation around the globe through the eyes of key market players.

As economies and global pharma emerge in 2023 from the negative macro impacts of the last 12-months, the overall picture for innovation has dramatically improved from survey results taken just eight months ago.

In fact, new record highs have been reported, with confidence in the United States, Germany and the UK notably outperforming all other countries. Germany (9.1) in particular appears to have weathered recent storms particularly well and has once again moved alongside the USA (9.3) – with both countries achieving scores above 9. The first time either country [or any country] has achieved these scores in the survey's history. The UK (8.5) has also continued trends of recent years and seen another dramatic improvement in innovation score.

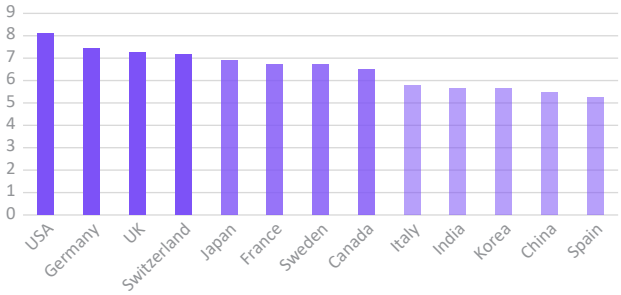
One country that has continued to see a gradual fall down the rankings in recent years is Japan – which despite an increase to 7.2 (from 6.8) six months ago – has fallen further back to 6th place. This could be a reflection of recent concerns over a "drug lag" as approvals decrease in the face of government policies designed to reign in the price of new drugs and therapies. Japan might therefore be perceived as a less attractive innovation hub than in the preceding decade as the government seeks to cut its reimbursement rates which make launching expensive new devices there more prohibitive – potentially to the detriment of prospective foreign partnerships or domestic innovation.[2] India and China have continue their dramatic 2022 improvements again rising by over and 30% and 35% in the most recent result – pushing aside other leading Western nations to be ranked as the best of the rest behind the top three.

January 2023 – Pharmapack Drug Delivery innovation score by country



Score the innovativeness of each country's drug delivery companies (1-10, 1 being the lowest, 10 being the highest)

May 2022 – Pharmapack Drug Delivery innovation score by country



Score the innovativeness of each country's drug delivery companies (1-10, 1 being the lowest, 10 being the highest)

May 2022 analysis

After record highs in 2021 driven by the unprecedented mobilisation of Governments healthcare providers and the global pharma supply chain in the fight against COVID, the Drug Delivery Innovation Index has contracted. This is the first loss of ground in the Index's 5-year history; however, the losses have mainly been driven by the scores of lower-tier markets (which were not all evaluated in many of the previous years).

Yet while the recent economic dislocation and uncertainties of the pandemic have passed through this year into industry sentiment, the overall market fundamentals remain very promising in the medium-to-long term.

The United States again leads the Drug Delivery Innovation Index, but its performance has declined marginally. A score of [8.1 vs 8.26 in 2021] sees a 2% reduction on 2021's Index score. Unsurprisingly, a cutting-edge drug development sector and the needs of an advanced domestic healthcare market continue to fire innovation in the world's largest drug delivery market not least as new, more sophisticated therapies necessitate novel packaging and delivery solutions.

Mirroring this trend are other Tier 1 markets. Germany [7.41 vs 7.69 in 2021] continues to lead the way in Europe followed by the UK [7.26 vs 7.39 in 2021] and Switzerland [7.15 vs 7.38 in 2021] and France [6.7 vs 7.1 in 2021]. Respectively, their scores declined by 3.5%, 2% and 3% and a surprising 5.5.% on 2021's performance.

[2] *https://www.fiercepharma.com/pharma-asia/japan-sees-drug-lag-as-foreign-pharmas-skip-market-amid-pricing-pressure-industry-group*

The UK's move up the European standings continues, now just behind Germany. Significant COVID-related positives in the innovation sphere appear to have locked into the British Government's long-term plan for development of the country's life science sector, its Life Sciences Vision. Tangible benefits already include regulator's working toward establishing an improved clinical trials framework.[3]

Overall, there is a clear suggestion the top three markets are now moving ahead of all other nations – with scores above anything seen in previous surveys.

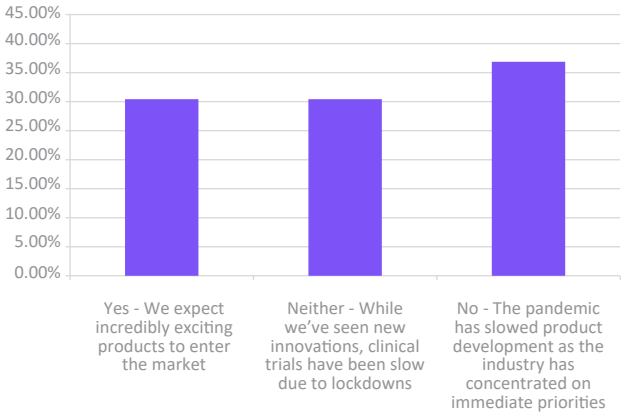
Industry direction: refocusing on innovation for the post-pandemic world

While reputations for innovation declined in the first half of 2022 following the boon of Covid-related demand. Just as economies around the world were waking up to risks associated with loose monetary policy, economic dislocation and surging inflation the latter half of the year has seen fears ease. With many market analysts even speaking of pent-up demand being unleashed in the year ahead – particularly in reference to contract services demand[4].

The complex effects of Covid on pharma markets over the past two years belie too simplistic an analysis. Covid has essentially had a riptide-like effect on global pharma. A colossal surge in demand challenged even the most expansive of supply chains. Drug delivery was no different with over 85% of respondents envisaging that pharmaceutical glass production will continue to be constrained in the next two to three years, mainly owing to unprecedented vaccine-oriented demand.

The reliance on the global pharma chain to combine with extraordinary speed to deliver life-saving solutions has clearly powered impressive growth. Yet, the massive Covid spike in demand was very narrow in focus and had little impacting on the wider innovation picture. The Pharmapack Survey bears this out with key drug delivery sector voices divided over whether 2022 helped accelerate device and packaging innovation:

Has 2022 helped accelerate device and packaging innovation?



Innovation has clearly been subject to significant disruption for many firms owing to the emphasis on vaccine development and delivery, and pressures and uncertainties caused by supply chain disruption and rising input costs.[5] Importantly, lockdowns and travel restrictions have hindered the all-important ingredient of partnership development leading, inevitably, to many projects being placed on hold.

However, as this report shows, it's vital not to lose perspective. The healthy fundamentals and emerging trends of the drug delivery sector are still there – and now returning quickly. So as pharma redeploys resources in a more certain market environment, the findings in most recent survey suggest the drug delivery sector's instinct for innovation that has served it and patients around the world so well over the years will return quickly in 2023. The slowing demand anticipated just 8-months ago may not be a reflection of the underlaying demand.

[3] *https://themedicinemaker.com/business-regulation/a-view-on-the-future-of-rd-from-the-uk*
[4] *https://www.outsourcedpharma.com/doc/CPHI-report-presents-shifting-outsourcing-realities-0001*
[5] *https://www.globenewswire.com/news-release/2022/04/22/2427173/0/en/Drug-Delivery-Devices-Market-Growth-Trends-COVID-19-Impact-and-Forecasts-2022-2027.html*

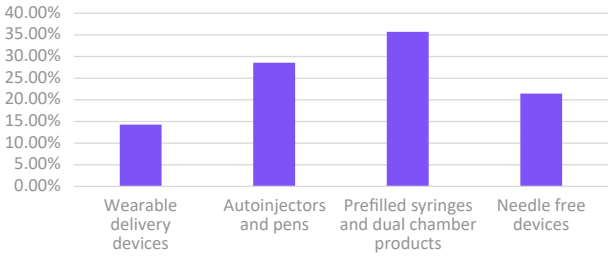
Chronic diseases affecting hundreds of millions worldwide, increasing therapeutic options, and growth in areas like biologics and biosimilars continue to support the case for strong upward moves in drug delivery through the next three years. Rising numbers of cancers, diabetes and respiratory patients will require regular drug delivery devices for diagnosis and treatment. Patient centricity and connected devices are exiting fields that are still emerging with a huge range of possibilities. Although COVID intervened, it has also brought new thinking and ideas about healthcare more generally as well as new ways of working and innovating.

Ultimately, there is a strong consensus among analysts around global growth in drug delivery markets is factored in. Valued at $258 billion in 2021, it is expected to reach $394 billion by 2027, all things considered this a staggering rate of growth when compared to nearly any other industry – it's a CAGR of 7.4% during the forecast period of 2022-2027.[6]

Novel Device outlook & innovation for 2023

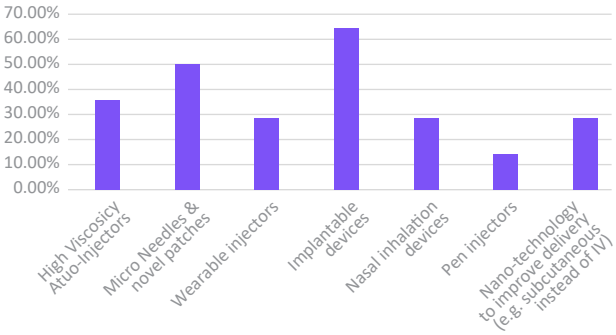
The Pharmapack 2023 Market Survey suggests confidence on the regulatory front with almost half of respondents believing up to five novel drug delivery devices or platforms will be approved by the FDA in 2023; a further 16% believe it could be as high as ten. Prefilled syringes and dual chamber products (36%) were seen as likely to receive the most approvals in 2023, followed by autoinjectors and pens (29%), needle free devices (21%) and wearable delivery devices (14%).

Which of the following injectables do you anticipate will have the most FDA approvals in the calendar year 2023?



Possibilities presented by biologics are one of the most exciting trends in pharma over the past decade. Drug delivery must continue to innovate to keep pace and smooth the commercialization of important new therapies to reach more patients. Pharmapack Survey respondents highlighted implantable devices (64%) and micro needles and novel patches (50%) as biggest areas of innovation to support growth in biologics over the next five years.

What drug delivery devices will see the biggest areas of innovation to support growth in biologics over the next 5 years? (tick as many as appropriate)



Implantable devices (64%) were identified as the delivery devices that will see the biggest innovation over the next 4 years, with industry reports predicting market share will reach $41 billion by 2026 with a CAGR of 7.27%.[7] This is not surprising given recent developments such as polymeric implantable devices, and the evident benefits of controlled drug release at a targeted site while minimizing toxicity risks and reducing dosing frequency. But most crucially, implantable devices are becoming more patient friendly, while also largely removing the patient's input from the adherence equation.[8] Micro needles – e.g. for subcutaneous mRNA delivery – and novel patches (50%) came second and recent news has suggest a broad field of applications. For example, that could include therapies for hard-to-reach, large-area full-thickness skin wounds caused by events like burns or surgical trauma.[9]

[6] *https://www.globenewswire.com/news-release/2022/04/22/2427173/0/en/Drug-Delivery-Devices-Market-Growth-Trends-COVID-19-Impact-and-Forecasts-2022-2027.html*
[7] *https://www.technavio.com/report/implantable-medical-devices-market-industry-analysis*
[8] *https://www.azolifesciences.com/article/Stuck-In3b-Role-of-Implants-in-Drug-Delivery.aspx*
[9] *https://www.frontiersin.org/articles/10.3389/fchem.2022.838920/full*

"For respiratory viruses like Covid-19, nasal vaccines are being looked at because this is the site of entry of the pathogens, so rather than relying on systemic action of the vaccine through parenteral injections, we can aim to achieve direct nasal mucosal immunity so that as soon as the virus enters the nose our body can initiate the immune response and prevent migration to the lungs. There is an approved intranasal flu vaccine (AZ's Flumist™ Quadrivalent), so the concept has been proven, but it is quicker and easier to formulate a vaccine by injection so some companies start there and then look to reformulate once they have confidence in the efficacy of their product. This is also the rationale behind developing intranasal prophylactics and therapeutics for these viruses, as well as for the treatment of CNS indications, targeting the direct nose to brain delivery pathway."

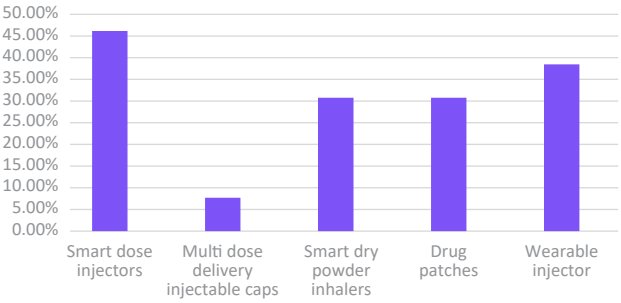
Gemma Budd
Director of Business Development at
Nanopharm – an Aptar Pharma company

Patient centricity continues to be the name of the game

In 2023 there is predicted to be even greater need for therapies and treatments to be delivered at home. This brings a whole new dimension into consideration during development; the importance of user-experience for patients, but also how they can be trained in their use.

The Pharmapack Survey results echoed this trend and the most important consideration when manufacturing 'patient-centric devices' was deemed to be patient adherence and ease-of-administration (79%). This was followed by size and portability of devices (57%), minimizing pain involved (21%), removing the need for patient training prior to use (21%), and decreasing the number of dosing events (28%). As a result of these trends in requirements, a significant proportion of respondents envisage double-digit annual sales growth in smart dose injectors (46%), wearable injectors (38%), smart dry powder inhalers (31%) and drug patches (30%).

Which of the following devices to do anticipate will see double-digit annual growth in sales in 2023 (tick as many as appropriate)



Increasing numbers of diabetes patients around the world mean this is an obvious outlet for injectable technologies. Developments continue apace in continuous glucose monitoring (GCM), with expanded wear-times and improved accuracy.[10] Insulin delivery also looks set for a big 2023: to take just one recent example, Insulet announced last January (2022) that it received FDA clearance for its Omnipod 5 automated insulin delivery system – the first tubeless automated insulin delivery (AID) system that integrates with a Continuous Glucose Monitoring (CGM) System and a compatible smartphone.[11]

[10] *https://www.drugdeliverybusiness.com/diabetes-tech-is-off-to-a-hot-start-in-2022/*
[11] *https://www.drugdeliverybusiness.com/fda-clears-insulets-next-generation-omnipod-5-wearable-insulin-pump-patch/*

Making the connection

It is well established that the logical extension of patient centric solutions is the introduction of connectivity to allow clinicians to use the presence of smart devices in patients' homes as a conduit for information flows. Patient outcomes can be improved significantly through data-driven management of adherence. Other benefits include reduction in costs for healthcare providers and delivering a more competitive offering.[12]

Connectivity has already become a ubiquitous part of modern life from TVs and fridges to fitness-related body sensors. The question for the drug delivery sector is not 'if', but 'how' to bring it to bear.

> *"A lot of companies are still adding connectivity without fully considering what they might get out of it, although many more are now starting to think more clearly about the benefits. Key areas that manufacturers are looking at are 'in the field' device diagnostic information. So, for example, they can receive bug reports from users directly and identify device failures in the field. We're also seeing more users wanting to look at their own healthcare data via their smartphones or connected devices. This data can also be passed through to health care providers, allowing clinicians to confirm if patients are taking their medications at the correct frequency, for example. Within diagnostics, we are seeing more cohesive thought around how to get a more integrated view of things. It's beneficial to be able to share data to multiple clinical sites, with cloud connectivity being a useful tool to achieve this."*
>
> **Thomas Watts**
> Engineering Consultant, Team Consulting

The global connected drug delivery devices market size was valued at a modest $214 million as recently as 2020 and is expected to grow at a staggering CAGR of 46.7% from 2021 to 2028 to around $4.5 billion.[13] This trend has been boosted by global take-up of COVID-related smartphone apps enabling symptom checking, test reporting and status verification. The standardisation in particular across Europe, among all age groups has improved acceptance and tolerance to healthcare data.

Thinking longer-term, almost two thirds of Pharmapack Survey respondents see cloud computing and smart packaging facilitating real-time adherence data as the technology likely to yield the biggest impact on pharmaceutical packaging and supply chains. But the findings show industry thinking on the main area of risk accompanying connectivity, data security. 52% of respondents agreed that it will become a significant hurdle over the next three-to-five years and that there are still huge complexities, especially in terms of regulation to work through.

Experts are clear that there's a need for dedicated focus on innovations around patient care being twinned with those addressing security concerns.

[12] *https://drug-dev.com/connected-delivery-five-perspectives-on-connected-drug-delivery-devices/*
[13] *https://www.grandviewresearch.com/industry-analysis/connected-drug-delivery-devices-market*

"Realistically, we have to assume that any device that can be attacked, will be attacked. If someone attacks your medical device, they can use it to send bad data to act in a negative way on your connected device. They're unlikely to be able to directly hack your cloud server, but they can send some data that has targeted effects and negative outcomes. For instance, that might be trick the owner into believing there's no problem with their health, or even manipulating health data. If you're manipulating an individual's health data, it could induce the wrong treatment which could potentially harm or even kill them (in the most extreme case). So, we must assume that cyber security is a very real risk during development."

Thomas Watts
Engineering Consultant, Team Consulting

Sustainability: Risk or opportunity?

The move toward patient centricity through smart packaging and devices, turbocharged by the potential for connectivity to yield further clinical benefits is an innovation gold mine; but what of the challenges this presents to industry sustainability goals? More complex packaging and devices with electronic components might represent steps forward, but the potential for wastage – particularly, in limited-duration use products – is a step backward.

Pharmapack Market Survey respondents considered which would have the biggest bearing on product development over the next 3-years. The vast majority – over 90% – cited sustainability, but interestingly, most respondents within this group (50%) believed a balance is becoming possible. Drug delivery innovators will look increasingly to prioritise both greater patient centricity and connectivity, and sustainability by seeking solutions though better recycling and improvements to product lifespan, including modularization. To give just one example, Aptar Pharma launched a HeroTracker Sense last year, a novel digital respiratory health solution that transforms a standard pressurised metered dose inhaler (pMDI) into a connected device for chronic respiratory diseases such as asthma, COPD, and Cystic Fibrosis – thereby making it reusable[14]. Another important consideration is that such solution that does not directly impact device design also comes with the advantage of not requiring a new regulatory (as it sits on top of the existing delivery system). Consequently, 'add-on connectivity options' like this can be brought to market far more quickly; perhaps nearly in line with the electronic tech development cycles of year-to-year improvements – verses 7 years of development on average for medical devices.

Although 70% of respondents believed the focus on the pandemic in the last few years slowed sustainability goals in pharma, longer term growth potential is evident, and they expected a dramatic rebound of focus in 2023. In fact, in five years-time, respondents expect investment in eco-packaging to have increased markedly; 38% believe it will increase by up to half, 15% double and a further 23% expecting a remarkable tripling of investments.

[14] *https://www.aptar.com/wp-content/uploads/2022/02/PR-February-8-2022-Aptar-Pharma-Launches-HeroTracker-Sense-1.pdf*

"Changing regulations is also likely have a big impact over the next five years in the drug delivery space. Sustainability will likely be one of the key drivers for regulatory change, as the industry continues to explore ways to mitigate its environmental impact and support the global response to climate change."

Brennan Miles
Managing Consultant – Drug Delivery, Team Consulting

Biodegradable packaging

Around half of respondents considered that biodegradable packaging is likely to be a key component of the effort to meet the industry's sustainability challenges. A further 29% agreed in part but placed greater emphasis on the need for a complex web of initiatives to make the industry greener.

Sustainability Index

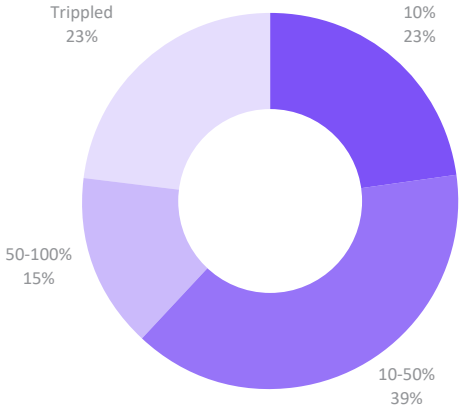
Pharmapack's Sustainability Index gauges the perception of how much is being done by each country in terms of plastic use, waste reduction, device recycling and which has the most progressed approach to sustainability. It provides a view of how far along each country is in terms of achieving optimal sustainability of pharma devices and medicines.

Encouragingly, industry reputations have held up well and actually improved narrowly as we enter 2023, with the overall average Sustainability Index score up by 3.5% (since the last survey in 2021). In a year when industry has often focused on other priorities, this is particularly encouraging for the future.

There have been some notable moves, Canada in its inaugural year slots in just behind the leading European nations and ahead of the United States. The 2021 leader, Sweden has experienced a marginal decline in score (from 6.8 to 6.6) while Germany saw a notable improvement (7.0 compared to 6.7 in 2021) overtaking Switzerland to lead the Sustainability Index. The UK (6.3) and France (6.2) both also saw marginal improvements consolidating their positions just behind the global leaders.

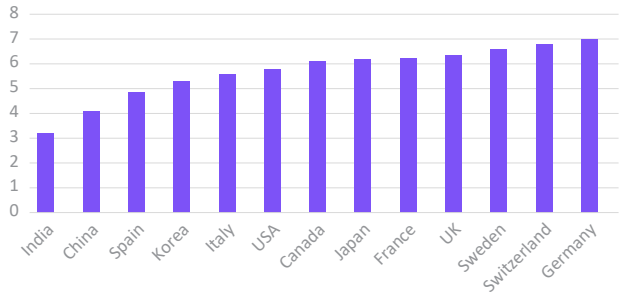
Mirroring its overall Innovation Index scores, but perhaps much more surprising, Japan experienced a decline in sustainability reputation (from 6.7 to 6.2), while the US (5.6), India (3.2) and China (4.1) remained in line with their 2021 scores. The most telling statistic is that unlike in all other areas of CPHI and Pharmapack research the top 5 European nations all remain above other regions – including the US, which to trail behind the EU in this aspect of pharma supply. While in Europe at a national level, Spain and Italy are perceived to lag behind the other larger nations in terms of adoption – despite ongoing centralisation of regulations from the EU.

Eco-packing is a current buzz word, in 5-year's time, how much do you anticipate investment in this area to have increased by?



We anticipate this is just the beginning of larger long-term story, and that we will see dramatic increases in these global scores over the next 3-years – particularly as pandemic priorities fade and the global push towards net zero goals take centre stage. Of the leading pharma nations, China and, in particular, India remain a long way back and without a year-to-year improvement. Our experts suggest this may well become a big drag factor on both countries growth prospects for their pharma industries in the medium term.

How far long each country is in terms of achieving optimal sustainability of pharma devices and medicines: in terms of device recycling, plastic use, reduced wastage. (1-10, 1 being the lowest, 10 being the highest score)



Conclusions

With two Pharmapack Europe events inside eight months and therefore two industry surveys we were able to track much more closely the changing sentiment in a year of great global turbulence. The results from survey May 2022 presented a clear picture of uncertainty from the war in Ukraine, a lack of capital resources globally for investment and of course surging inflation in the majority of nations. But this year's later survey has shown how resilient, flexible and robust the overall market remains and the industry is quickly looking ahead to a much more prosperous 2023 – with the United States, the UK and impressively, considering its energy issues, Germany recording record results. Therefore, we expect 2023 to be the first year that normal development and growth returns to the majority of major markets – becoming free of legacy drag factors from the pandemic. While this report makes no comment on what it might be, it is also likely that the Ukraine situation will have reached some kind of resolution in the year ahead.

So what does that mean the priorities will be 2023? Our experts and results therefore point to device, delivery and packaging companies returning to sustainability as the industry's number one priority. Companies are grappling with the intractable question of how to speed innovation, lower costs while improving sustainability – clearly no easy challenge to address. But the next 18-months we are also likely to see mRNA technology and biologics mature further with both new devices and even novel modes of delivery created for mRNA in particular. The vaccines for mRNA were developed as quickly as possible, however it's now likely the industry will hone delivery of this platform in the next 2-3 years.

The other key insight from the findings is a wake-up call on the importance of getting the drivers of innovation back on track immediately. Biologics-inspired novel delivery systems, solutions that assure high levels of adherence through ease of administration and cloud-connected modularization of existing devices are just a few areas of evident growth potential.

Supply chains have also become much more robust and 86% of Pharmapack Survey respondents say there will be a prolonged acceleration of regionalized/localized supply chains for drug delivery and packaging over the next two to three years.

Overall, the results in this survey, often an early marker of the trends and economics ahead for global devices, pharma and packaging are extremely positive. The direction of travel of strongly suggest that despite a very difficult 2022, the next year will be a year of stronger results, innovation and growth than perhaps anyone was expecting.

Part 2

Pharmapack 2023 is a shop window for US raiders looking for European packaging assets

Gregor Nischer
Managing Partner
MP Corporate Finance GmbH

Ahead of Pharmapack Europe 2023, which returns to its traditional February timing for the first time since the start of the pandemic, we caught up with Gregor Nischer – MP Corporate Finance GmbH Managing Partner – to get his insights into what the year ahead holds for the packaging market in terms of consolidations and partnering. He points to the recent trend for many pharma companies to increasingly only work with larger companies and the effects this is likely to have on the shape of the market over the next few years. In particular, he explores how a majority of smaller and medium packaging companies are going to need to grow towards or beyond €100 million turnover per year mark, with those of 20 million or less particularly exposed to potential acquisitions.

In his session on the opening day (February 1st, 2023) – where more than 5500 attendees and 300 exhibitors are expected – Nischer will look into why 'size matters' and 'what is behind the key drivers for consolidation in pharmaceutical packaging'.

Background – does size matter for pharma packaging companies?

"In the last few years, size requirements have become an increasingly key driver for the consolidation, and this is in part a reflection of regulatory changes and the growth of pharma companies who are looking for improved supply chain security. Pharma customers like to have suppliers they can reply upon for more than single components (e.g. cap, bottles etc) and increasingly want providers than can provide complete solutions. At the same time, regulations are becoming more complex, and small companies don't have the necessary resources meaning the development of products is becoming prohibitively expensive."

The other significant aspect is that many companies are looking to sell products globally meaning the smaller suppliers are further challenged with having the significant divergence of multiple regulatory burdens and this can become unmanageable. In fact, a notable trend had been the recent spate of acquisitions of larger – albeit not larger per say – USA manufacturers buying European based manufacturers to gain a foothold here.

I think this is driven by three reasons. First, the customer base is getting bigger and bigger and with the bigger customer base they have higher requirements meaning the ongoing consolidation in the pharma field also drives to requirements for packaging suppliers. Second the regulatory environment get tough and tougher every year and third the packaging industry is a rather old industry, if you look into the plastics packaging, and also there a consultation trend has to develop in the end to keep fit."

What are the benefits/ disadvantages of a fragmentated sector – does it have any effect on innovation?

"I doubt it has impact on innovation because innovation is capital intensive and you have to have a certain size to be innovative. What less fragmentation might do, as economies of scale take hold, is make the supplier less and less flexible to individual pharma requirements. It is much more difficult to do when you have higher throughput and more customers, so product standardisation rather than individualisation is likely. A smaller company is more likely to want to do 'anything' to keep the contract and make those unique specification adjustments."

Why are pharma customers putting suppliers under increased size pressures?

"The single biggest reason is that they want improved supply chain security and global suppliers and packers can offer the possibility of multiple market sourcing, a large supplier is also more likely to be reliable and robust in a crisis."

Could strategic alliances be the solution to these trends?

"A cooperation you do see sometimes is for a couple of smaller providers, such as a XXXX manufacturer intensively cooperating with a glass or bottles producer. Together they want to be able to sell a solution to the pharma customer. However, its more preferable for these smaller companies to 'acquire in' the assets or 'buy in' the products so that they can be the sole seller and responsible company to their pharma customer. Working in a collaboration, despite offering essentially the same end product, is far less attractive for the pharma customer as it introduces a less clear route of responsibilities – i.e. in the event of complexity who is to blame.

So what does all this mean for the immediate future in the year ahead. Pharma is a slower moving industry so we won't see dramatic shifts rather a methodical and steady change as we see less smaller and nimble companies and more medium sized groups built through acquisition. In terms of ownership, the trend thus far is for US buying European – and this is mostly a reflection of there being more number of larger companies in the USA. So if we look at the European market solely through the prism of turnover, I think we could say those companies with a turnover of €80 million or above, I would think are broadly safe. Those with less than €20million are highly vulnerable, and those between €20 and €70 million should be looking at their options in terms of how they can acquire and build towards the €100 goal. These are of course also potentially the most attractive assets for investors, and I think this is where you will see the biggest movement in the year ahead. How can these companies be delivered the capital to grow out and acquire complementary assets – potentially in other continents. I would therefore also imagine that Pharmapack Europe itself is potentially a very big shop window for many of these US investors and companies looking for entry into Europe."

Part 3

Packaging & Delivery - Trends Roundtable

Team Consulting

Ahead of Pharmapack Europe 2023 we spoke with Team Consulting's entire team to get a view on the big trends and changes in the market ahead. Here is a breakdown of everything they expect:

Patient centric opportunities in biologics

"There are lots of very interesting new and developing therapy areas to keep an eye on throughout 2023. One of the most rapidly evolving fields is in biologics. These innovative medicines are used to treat the root cause of many complex diseases in areas such as rheumatology and oncology, but are also used in cardiology, dermatology, gastroenterology and neurology, among others. In addition, sector growth in biosimilars has an important role to play in the democratisation of healthcare, enabling more global access to treatments at a lower cost.

The major challenges in biologics however are both the high treatment costs - largely driven by complex manufacturing processes - and complications around transport/storage and drug administration. Factors such as a need for low temperatures during shelf-life storage and a requirement to deliver in high volumes, often by intravenous infusion, are all challenges that need to be overcome. To realise the opportunities in this space, there is a need to simplify the manufacturing processes and produce drugs that can be stable at higher temperatures, while also simplifying the therapy administration process to improve access for a wider range of patient and income groups.

Another trend we are seeing is the rise in patient centric approaches steering new formulation decisions in this sector. The 'market pull' is for simple, at home, subcutaneous administration of therapies such as oncology treatments that would have previously only been available as a large volume infusion in a hospital setting. This in turn is highlighting the need for new delivery systems such as high-volume injectors and wearable, on-body delivery systems, that can meet the requirements for routine self-administration of more concentrated biologic therapies.

The key to developing devices to suit this need is through a combination of deep understanding of mechanical requirements (and trade-offs) to accommodate increased formulation viscosities and higher payloads. Careful behavioural science input into the design will also be needed to ensure that the device solutions are easy to use as well as being safe and effective.

Ultimately, in 2023 we can expect to see a continued focus on novel technologies for delivery of higher payloads/viscosities for self-injection, as well as a continued demand for other low-cost devices to suit generic therapeutic applications for both the respiratory and injectables markets."

Brennan Miles
Head of Drug Delivery, Team Consulting

The move to hybrid healthcare in post-pandemic populations

"Over the past few years Healthcare professionals (HCPs) have been noting a massive growth in digital tools, however these tools are not replacing in person care, rather they are augmenting it. Many of the digital approaches that were used at scale during the pandemic, such as telehealth in GP surgeries, have continued and have become an expected part of the patient journey. While these digital tools became mainstream through necessity, their continued use post-pandemic has been an important step towards increasing the adoption of other digital solutions more widely. Previous concerns around patient access to the technologies required to enable digital solutions also appear to be diminishing, with the number of smartphone subscriptions worldwide surpassing 6.5 billion in 2022 and predicted to rise to 7.5 billion by 2027[15]. The pandemic proved to be a steep technology learning curve for many populations, owing to the use of government issued apps requiring people to scan QR codes and upload test results digitally. As smartphone usage continues to proliferate, the key for medical device developers will be to ensure that any digital experiences they introduce are easy to use, add value, and are accessible to all user groups."

Ben Cox
Head of Digital Design, Team Consulting

Wider horizons for medical device sustainability

"As sustainability increases in importance across the industry, the horizons that are being considered are widening. Historically, many discussions around device development have been focused on material selection and incremental improvements to existing architectures and business models. As net zero targets begin approaching for pharma companies, healthcare providers and governments, more radical approaches are needed to achieve these in time. Drug delivery is mirroring the wider world, with a trend towards not just product sustainability, but also the total impact, through scope 2 and 3 emissions[16]. This is forcing all parties to look further afield at their supply base to understand the impact that those businesses have. In the device field, a wider consideration of reusable and re-processable devices, falling under the circular economy grouping, is again widening the horizon of what is possible and, more importantly, what is actually needed by patients. Furthermore, consideration of the whole lifecycle needs to be planned in from the beginning of the development to ensure the maximum gains can be made, for example designing to minimise interim transportation packaging. As new medical devices and technologies can often take upwards of 5-7years to reach the marketplace our expectation is that we wont see any pivotal changes on this topic in 2023. However, we do expect that pressure will continue to ramp-up (particularly around new developments) to make sure that sustainable development strategies are included and documented as part of the planning process thus putting into action the groundwork for more sustainable devices in the future."

Alastair Willoughby
Head of Mechanical Engineering, Team Consulting

[15] *https://www.statista.com/statistics/330695/number-of-smartphone-users-worldwide/*
[16] *https://ghgprotocol.org/sites/default/files/standards_supporting/FAQ.pdf*

Pharma companies placing increasing focus on user-based design

"Having a device that not only functions effectively but that provides a positive user experience can play a significant role in improving patient adherence and clinical outcomes. A human factors programme is much more than a regulatory tick box exercise. Adopting a truly user centric design process is essential to develop products that meet the practical and emotional needs of our users. In line with this, pharmacos are placing increasing importance on the user experience and the need to understand their patient's behaviours, beliefs and needs. A 2022 survey of drug delivery professionals by Team Consulting, found that 25% of respondents felt that understanding the unmet needs and challenges of their customers was one of their biggest challenges at the start of a development.

This could in part be related to the recent shift in many drug payment models from a focus on volume to a focus on value for the patient[17]. These outcome-based contracts, whereby treatment payments are linked to positive patient outcomes, are encouraging drug manufacturers to take a more proactive approach to ensure and demonstrate the effectiveness of their products in the wild. While the most important patient outcomes are of course health related, patient quality of life is also another key factor. In order to achieve both, pharmacos need to ensure that both the treatment and the device used to deliver it meet their patient's needs."

Paul Greenhalgh
Director of Design, Team Consulting

What the proposed changes to the MDR mean for the industry

"On the 6th of January 2023, the European Commission published a proposal to amend the European Medical Device Regulation (MDR) with respect to the transitional provisions for certain medical devices, which are currently due to end on the 26th of May 2024. The proposed amendment seeks to delete the 'sell off' deadline contained within the MDR, thereby allowing devices placed on the market after the end of the transition period to continue being sold until their actual expiration date.

This proposal is being driven by a realisation on the part of the European Commission that the current overall capacity of notified bodies remains insufficient to carry of the tasks required of them, coupled with the fact that many manufacturers are not sufficiently prepared to meet the strengthened requirements of the MDR by the end of the transition period. This lack of capacity has been identified as a real threat to the continued availability of medical devices on the EU market. The Commission's proposal identifies a total of 36 notified bodies currently designated under the MDR; with a further 26 applications currently being processed. As of October 2022, notified bodies reported they had received altogether 8,120 applications from manufacturers for certification under the MDR and had issued 1,990 certificates in accordance with the MDR.

Based upon an estimate presented by notified bodies to the Medical Device Coordination Group (MDCG) on the 17th of November 2022, the number of certificates issued by May 2024 may only reach around 7,000 if the current rate of certificate issuance remains the same with no changes to current conditions in stark contrast to the near 25,000 valid certificates issued under the AIMDD and MDD that will expire before the 26th of May 2024.

[17] *https://joppp.biomedcentral.com/articles/10.1186/s40545-022-00475-3*

Faced with this significant shortfall in capacity, it seems inevitable that the European Commission had to act to maintain the supply of medical devices into the EU market. The deletion of the 'sell-off' deadline will further ensure that safe and effective devices remain available beyond the arbitrary date applied. This will mean that manufacturers and distributors won't have to engage in extensive stock build to maintain supply of devices after the May 2024 deadline. Distributors will also not be under pressure to sell on devices that will have to be scrapped after the 12 month sell-off window closes. The change will also avoid potentially significant numbers of devices simply being withdrawn from the EU market due to the manufacturer's EC certificate issued under the MDD having expired, which will be significant for manufacturers mainly operating in the EU market that have not had time to transition due to constraints on notified body availability."

Ian Wilde
Director of QA & RA, Team Consulting

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