

DRUG DELIVERY TRENDS FOR 2024

In this article, Tom Oakley, Vice-President Design and Development, and Kamaal de Silva, Principal Engineer, both of Springboard, consider how keeping abreast of the latest trends can help the industry predict and prepare for the future and, commenting from the company's privileged position at the centre of many of the drug delivery sector's most exciting developments, discuss the top trends to look out for in 2024.

THE BOOMING MARKET FOR WEIGHT MANAGEMENT DRUGS

Delivery devices for weight management drugs such as GLP-1s are, unsurprisingly, attracting huge development interest and funding. Originally developed to treat Type 2 diabetes, several GLP-1s have been approved for weight management and weight loss since Saxenda (liraglutide, Novo Nordisk) was approved in December 2014 (Table 1).¹

The GLP-1 market is forecast to increase at 6.1% compound annual growth rate from 2021 to 2028, from a starting point of US\$12.7 billion (£10.0 billion)

“With the new GLP-1s in development, and the biosimilars coming to market, there is substantial opportunity (and funding) to develop better delivery devices.”

in annual sales.² This projection may be conservative if GLP-1s are approved for additional indications, such as reduction of cardiovascular disease.

Most GLP-1 drugs need to be injected, but some oral GLP-1s are coming to market, for example, Rybelsus (semaglutide, Novo Nordisk), which was approved by the US FDA in September 2019, and by the EMA in April 2020.³

The first GLP-1s to come to market used repurposed insulin pens, or adaptations of existing autoinjector platforms. With the new GLP-1s in development, and the biosimilars coming to market, there is substantial opportunity (and funding) to develop better delivery devices.

CLOSED-LOOP INSULIN SYSTEMS (ARTIFICIAL PANCREAS)

Since the FDA approved the MiniMed 670G in 2016, there have been several new hybrid artificial pancreas systems approved by regulators for the treatment of Type 1 diabetes (Table 2). The essential components of such a system are a continuous glucose monitor (CGM), an insulin pump and an algorithm, where the latter can be

Drug	Dosing frequency			Brand name for each indication		
	Twice daily	Daily	Weekly	Type 2 diabetes	Weight loss	Company
Exenatide	X			Byetta		AstraZeneca
Liraglutide		X		Victoza	Saxenda	Novo Nordisk
Lixisenatide		X		Lyxumia		Sanofi
Semaglutide (tablet)		X		Rybelsus		Novo Nordisk
Semaglutide			X	Ozempic	Wegovy	Novo Nordisk
Tirzepatide			X	Mounjaro	Zepbound	Eli Lilly
Exenatide			X	Bydureon		AstraZeneca
Dulaglutide			X	Trulicity		Eli Lilly

Table 1: Example GLP-1s and their brand names for diabetes and weight management indications.



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Approved in Europe	Approved in the US
Medtronic 780G CamDiab CamAPS FX Diabeloop DBLG1	Insulet Omnipod 5
Medtronic MiniMed 670G/770G Tandem t:slim X2 pump with Control-IQ technology	

Table 2: Hybrid closed-loop systems approved for Type 1 diabetes in Europe and the US.⁴

implemented in the pump itself or on a separate device such as a mobile phone.

The time taken to develop, validate and launch these systems has prompted some people to adapt or develop their own DIY closed-loop systems, an example being the Nightscout project, which uses the tagline #WeAreNotWaiting.⁵ The risks of using systems that have not been through regulatory approval are being addressed by initiatives such as Tidepool, which achieved FDA clearance for Tidepool Loop in January 2023.

High costs are also a large factor in driving users to DIY systems.⁶ However, approved systems will be provided by an increasing number of public health providers, such as the UK NHS, over the next few years.⁷ This increase in user base should lead to increased interest and investment in 2024.

The significant market for diabetes management has fuelled significant innovation in closed-loop delivery systems, but similar technologies are expected to be applied to a range of indications outside

of diabetes where self-monitoring and self-administration can bring benefits for patients and payers.

LARGE-VOLUME INJECTION

Large-volume injection continues to be a hot topic due to the formulation requirements of some new biologics and the preference to move some therapies from intravenous infusion to subcutaneous injection. There are two main categories of delivery devices for large-volume subcutaneous injection:

- On-body delivery systems, also called patch pumps, bolus injectors and other names
- Large-volume autoinjectors.

Relatively recent approvals of on-body delivery systems include Alexion's (MA, US) Ultomiris® (ravulizumab-cwvz) in the West (PA, US) SmartDose platform in September 2022,⁸ and Apellis Pharmaceuticals' (MA, US) Empaveli® (pegcetacoplan) in the Enable (OH, US) enFuse platform in September 2023.⁹ There are many other on-body delivery systems in development, with some on the market.¹⁰

The biggest change in the past year, and the biggest question for 2024, is the emergence of large-volume autoinjector platforms. Most autoinjector platforms are based on a 1 mL staked needle and, in recent years, 2.25 mL syringes have started to be supported. The increasing capability for larger volumes has been extended to 3 mL in cartridge-based autoinjectors, such as Gerresheimer's (Düsseldorf, Germany) Inbeneo or SHL Medical's (Zug, Switzerland) Maggie platforms.

In the past year or so, several autoinjector families have been extended to 5.5 mL, such as Ypsomed's (Burgdorf, Switzerland) YpsoMate 5.5 (based on a syringe)¹¹ and Maggie 5.0 (based on a cartridge).¹² The question is how much these 3 mL and 5 mL autoinjectors will eat into the market for on-body injectors.

OPHTHALMIC INJECTIONS

Ophthalmic injections have specific requirements that mean that standard injection systems are often inappropriate, such as:

- Very low particulate limits
- No suction
- Minimal increase in intraocular pressure
- Difficult access and targeting
- Small dose volumes and strict dose accuracy.

The ophthalmic drugs in development, and the new solutions that they require, have created a steady stream of device innovation over recent years that is expected to continue, or even increase, in 2024.

The ophthalmic drug delivery market is split roughly equally between topical applications and injections, so it is important to remember the innovation opportunities for topical applications such as eyedroppers or, more recently, spray devices. The usability of preservative-free eyedroppers could be improved, for example, by reducing their squeeze force, reducing the chance of multiple drops and assisting alignment with the eye.

NEW DEVELOPMENT BUDGETS FOR 2024

Every annual cycle comes with its changes to budgets, so why raise the subject for 2024? The reason is that the healthcare industry went through a substantial boom from mid-2020 through to late 2021, or perhaps even mid-2022 (coined the "covid dividend"),¹³ and a market correction since then.

The healthcare industry has faced significant headwinds since the middle of 2022, including:

- The full-scale Russian invasion of Ukraine leading to shocks in financial markets and some supply chains
- Energy prices increasing substantially
- High inflation pushing up wages and other costs (Figure 1)

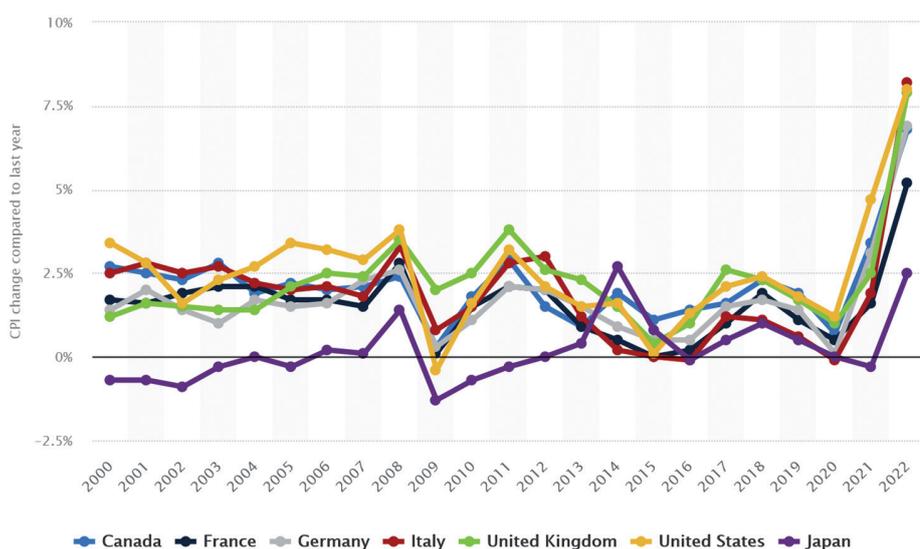


Figure 1: Annual inflation rates in G7 countries from 2000 to 2022.¹⁴

- The sales of various covid-19 mitigations reducing substantially, such as vaccines, other covid-related drugs, personal protective equipment, certain diagnostics, critical care equipment and so on.

These headwinds led to waves of redundancies and budget cuts through 2023. With inflation reducing in leading economies (Figure 2) and the industry having made corrections for the other adverse factors, there is cautious optimism that 2024 will return to increased investment in R&D and innovation.

Some companies are displaying corporate agility and moving back towards investment for 2024. Fast-forwarding to the end of 2024, it can be expected that those agile companies will have a competitive advantage over those that continue to restrict investment in R&D.

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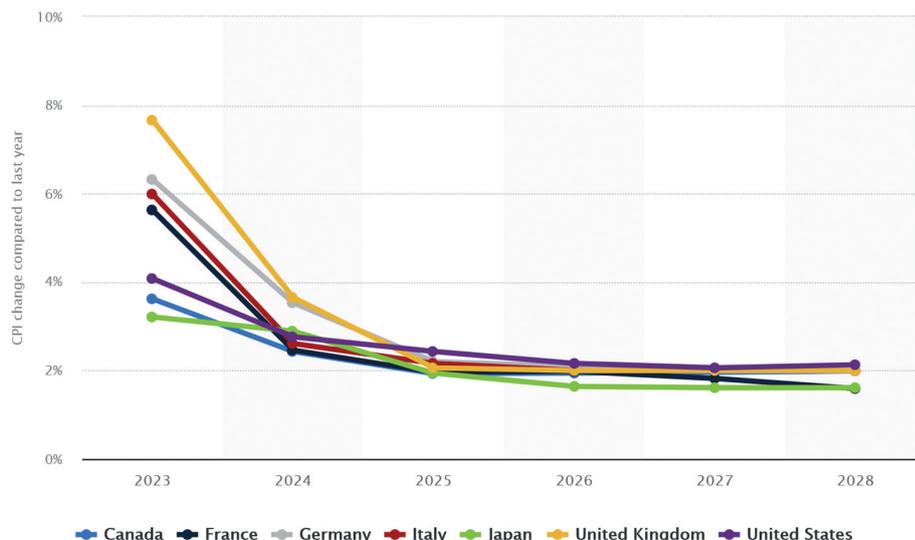


Figure 2: Forecast of annual inflation rates in G7 countries from 2023 to 2028.¹⁵

SUMMARY

Sales of GLP-1s are predicted to increase and the trend is expected to accelerate if new indications, such as reducing cardiovascular disease, are approved. This means there will be greater funding and demand for improved GLP-1 delivery devices.

Closed-loop diagnostic-and-delivery systems are maturing for diabetes. The principles involved could be applied to many other indications, perhaps with new devices and algorithms tailored to the different user needs and technical requirements.

New on-body large-volume delivery systems continue to gain regulatory

approvals and face competition from large-volume autoinjectors. Meanwhile, ophthalmic drug delivery is an area ripe for innovation in 2024, for both injection and topical devices.

Finally, 2024 promises to be a year of increased investment in drug delivery devices as companies emerge from the post-covid correction in healthcare sales and economists predict reductions from uncharacteristically high energy prices and inflation. It remains to be seen which companies are most agile in adapting to the new opportunities in drug delivery.

If you have questions or would like to discuss any points, please do not hesitate to contact the authors.

ABOUT THE AUTHORS

Tom Oakley leads engineering and scientific teams developing new injection devices, pumps and inhalers. He has been the named inventor on dozens of patents throughout his 25 years' experience in the drug delivery industry. His most recent work focuses on developing robust device strategies and plans for a wide range of clients from the largest multinationals to the most dynamic start-ups. Mr Oakley is a regular speaker at various international conferences on innovation and medical device development. He read Engineering at Cambridge University (UK) before becoming the Choate Fellow in Human Physiology and Pathology at Harvard University (MA, US).

Kamaal de Silva is an experienced engineer who has led design and development projects at Springboard on a range of drug delivery devices, including infusion pumps, on-body delivery systems, autoinjectors, pen injectors and soft mist inhalers. He is committed to developing innovative hardware and software-based solutions that enhance user experiences, improve healthcare outcomes and satisfy key business requirements. Mr de Silva studied Mechanical Engineering at Imperial College London (UK). The knowledge he has accrued throughout his career has led to a comprehensive understanding of design, manufacturing and scientific principles that he can leverage to create robust, risk averse designs.

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ABOUT THE COMPANY

Springboard is a technology and design consultancy, and forms Sanner Group's Design Centre of Excellence. Springboard creates and develops new products and technology, including products in the field of medtech and drug delivery devices, assisting companies in resolving technical challenges and decreasing time to market.

Sanner GmbH was founded in 1894. Headquartered in Germany and with best-in-class manufacturing facilities across Germany, France, Hungary and China, Sanner has successively developed from a global market leader for desiccant closures and effervescent tablet packaging into a sought-after provider of customised solutions in the areas of medical devices, diagnostics, pharmaceuticals and consumer healthcare. Today, Sanner supplies its products to more than 150 countries globally and has over 600 employees.

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