**RECENT MOVES TOWARDS CONNECTIVITY**

At a time when many industries have taken huge steps forwards into the implementation of connectivity, progress has remained slower in the pharmaceutical industry – particularly with drug delivery devices. However, the need to promote patient compliance has never been so great and technology is now more affordable, so increasingly moves are being made in the industry towards e-health.

A programme launched by the US FDA in 2016 states that “these advancements [in digital health] are leading to a convergence of people, information, technology and connectivity to improve healthcare and health outcomes”. Last month, for example, Otsuka and Proteus (Redwood City, CA, US) announced the first FDA clearance of a digital medicine system combining a pill and a sensor. This represents a big leap forwards in compliance monitoring.

In addition, both European and US agencies are working towards a simplification of the regulatory path for many connected drug delivery devices and the barriers that have surrounded such devices are vanishing.

There have also been countless connected innovations including electronic health record software, heart rate monitor patches, wrist bands that monitor blood pressure and insole sensors that measure weight, balance or temperature. It is clear that connected drug delivery systems are going to be a key part of healthcare in the future.

**OPTIMISING THE MANAGEMENT OF CHRONIC DISEASES**

In this context, Biocorp has developed a line of connected drug delivery systems with the main objectives of enhancing patients’ medical compliance and ultimately changing the way treatments are managed, without adding any burden to their daily lives.

Ongoing partnerships within the pharmaceutical industry, studies among patients and multiple awards given to our devices have shown that there is abundant enthusiasm for our products. In October 2017, Biocorp was awarded the CPhI award for “IT, mHealth and digitalisation” on its whole line of connected products. This award recognises of several years’ worth of work and acknowledges that there is a real need for connected drug delivery.

Biocorp’s line of connected devices is composed of innovative smart drug delivery systems, mostly dedicated to the injectable route of administration.
This includes the smart reusable pen injector Datapen™ and the connected cap EasyLog™ and that connects major pen injectors (Figures 1 and 2). We also develop connected medical devices in the respiratory field; including Inspair™, a smart sensor and communicator compatible with all pressurised metered dose inhalers (pMDIs) (Figure 3).

These devices are designed to be a cornerstone of future treatments for chronic diseases such as diabetes, multiple sclerosis, infertility, Parkinson’s, asthma and COPD.

Improving Compliance

Biocorp aims to improve patients’ lives by improving their medical compliance. Many patients suffering from chronic diseases must manage their treatment by themselves. Our connected devices are designed to give patients support and comprehensive tools that lead to a better understanding of their disease.

For instance, patients suffering from diabetes need to keep track of several factors, such as the last time they took their treatment or the quantity of insulin they injected. Using EasyLog™ helps by providing information such as exact dose injected, time, date and production concentration, as well as reminders and alerts. Trackers will also detect with 100% accuracy if the injection was not fully administered.

Furthermore, sensor devices from Biocorp can link with diagnostic tools such as blood glucose monitoring (BGM) or continuous glucose monitoring (CGM). The integration of blood glucose level together with the patient’s insulin information from EasyLog™ will revolutionise the way patients are managing their chronic condition. This is an exciting innovation and Biocorp is the only player in the market at this level of maturity.

MAKING DEVICES USER-FRIENDLY AND TRANSPARENT

The connectivity function needs to be available without adding burden to patients’ daily lives. Connected devices must be easy to use and simple to understand so that they can improve compliance. All our devices and applications are user-friendly and convenient. For example, with EasyLog™, patients only need to take their pen injector, clip EasyLog™ on the top of it and inject as per normal. It is an innovative product that, once attached, can give connectivity to all major pen injectors on the market without requiring any additional steps from patients.

The technology used by these smart devices is simple in appearance, yet the functionalities added through the implementation of connectivity are highly advanced. Biocorp has developed smart sensors and innovative ways to capture data that are trailblazing. Being able to connect to a pen injector and capture the exact dose with 100% accuracy depends on cutting-edge technologies (Figure 4, next page).

Security is a key issue as well; all data are encrypted in the device and thereafter transferred to a secure platform. No data is stored on the mobile phone and a strong authentication system is utilised. This offers a very high level of protection, compliant with European and US data protection laws. Therefore, Biocorp’s smart devices aim to bring “transparent connectivity” in order to improve the patient’s experience and medical compliance.

“P4” MEDICINE CONCEPT

Healthcare is evolving from reactive care to predictive, preventive, personalised and participatory care, known as “P4” medicine. Biocorp aims to play a key role in this type of care by creating a patient-centric, interconnected environment to which many stakeholders can contribute. To do this, we want to leverage connectivity to bridge the gaps between these different stakeholders and provide accurate information that will benefit everyone.

Personalised Medicine

In the field of diabetes, healthcare companies have been working hard to build closed-loop systems that will optimise treatment management for diabetics. EasyLog™, by automatically recording...
each amount of insulin delivered by the patient, with the exact time and date, produces key data that were previously missing. It allows healthcare professionals (HCPs) to better understand their patients and tailor treatment plans based on individual characteristics to guarantee maximum efficacy, fulfilling the promise of personalised medicine.

**Participatory Medicine**
This new data will be available for patients and sharable with HCPs and other stakeholders, at patients’ discretion. It is designed to be centralised in a single platform to make sure that everyone involved can have the best level of information to optimise their contribution. Biocorp truly believes in the benefits of participatory medicine and has been working hard on its interoperability with other systems to promote it.

**Preventive Medicine**
Accurate information will help preventive medicine by quickly identifying patients that are losing interest in their treatments and moving away from optimal treatment adherence. EasyLog™ data will encourage HCPs to discuss the treatment experience with patients, potentially adapt the medication plans to remedy the situation, and set up treatment adherence goals to get them progressively back on track. Adjusting patient behaviour will be a new strategy that HCPs can use before having to increase the dosage, leading to a more effective, and cost-efficient, system.

**Predictive Medicine**
The ultimate step of this new era will be predictive models. To build such models, you need accurate, consistent and relevant data. EasyLog™ is the only sensing system that collects 100% accurate insulin delivery information, with high robustness and repeatability. The quality of predictions is only as good as the data behind them, therefore Biocorp is highly committed to providing this level of precision. If predictive medicine manages to wipe out contingency and uncertainty, then the risks of severe complications, incidents and all their consequences (relapses, emergency doctor visits and hospitalisations) will be reduced to a minimum.

**CONCLUSION**
Patients face many challenges in the management of chronic diseases and this leads to poor compliance. Pharma companies must find ways to integrate connectivity into drug delivery systems to meet the challenges of patient compliance. Connected drug delivery devices are the missing link that makes automated chronic disease management possible as they bring real benefits to patients without adding additional burden.

Biocorp’s connected devices improve the patient experience and are designed to fit seamlessly into people’s daily lives, with the final objective of supporting the shift from a curative healthcare model to a preventive and predictive one.

**ABOUT THE COMPANY**
For 20 years, Biocorp has been designing, developing and manufacturing medical devices for the pharmaceutical industry, enhancing drug reconstitution, safety, packaging and delivery. Today, Biocorp continues to innovate in medical plastics, bringing new solutions to the market such as NewGuard™, an integrated passive safety system for PFS compatible with existing Nest & Tubs, and Biopass™, a reconstitution system with an integrated needle ready to inject.

Recognised for its expertise in device R&D, Biocorp has incorporated software development capacities to develop connected drug delivery systems, including Datapen™, a reusable smart pen injector that automatically transmits data to a treatment mobile app, helping patients to manage their treatment; and a range of add-ons, smart sensors for existing drug delivery devices (pen injectors, MDIs). Biocorp’s innovative connected products have received multiple awards: Pharmapack 2015, Pharmapack 2016, Frost & Sullivan 2016, E-health Summer University 2017 and CPhI award 2017.

On top of its R&D capacities, Biocorp also provides manufacturing services for plastic injection, process assembly and blister packaging.

**ABOUT THE AUTHORS**

**Eric Dessertenne** has worked for the pharmaceutical and medical devices industries for many years. He holds a pharmaceutical degree from the University of Clermont-Ferrand (France), an MBA from ESSEC Business School (Cergy-Pontoise, France) and is a graduate of the Therapeutic Chair of Innovation at ESSEC Business School. He began his career in the pharmaceutical industry working for Servier in France in the Corporate Strategy department and then moved to the Chinese subsidiary in Beijing, where he handled positions in the marketing and sales force department. Mr Dessertenne then joined LEK Consulting where he worked as a consultant in the Life Sciences and Private Equity practices. In 2014, he brought his experience and insights on market opportunities to Biocorp as Head of Business Development & Commercial Operations.

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Give your existing device the benefit of connectivity.

With over 20 years of designing and manufacturing medical devices for the pharmaceutical industry, Biocorp knows precisely how connectivity gives you better data, leading to better treatment and better patient outcomes.

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