H&T PRESSPART

THE FUTURE OF CONNECTED ASTHMA AND COPD CARE: A STEPWISE DEVELOPMENT

In a continuation from his previous article in *ONdrugDelivery Magazine*, Benjamin Jung, PhD, Program Manager, eMDI, H&T Presspart, outlines possible scenarios for the likely steps in the development and adoption of connected devices in the field of asthma and COPD care, revisiting H&T Presspart's eMDI and Quantum dose indicator.

INTRODUCTION

Picking up from our June 2017 *ONdrugDelivery* article "Embedded Connected Metered Dose Inhalers Meeting Requirements for Mass Adoption",[1] steps taken to counter non-adherence to asthma and COPD medication remain insufficient,[2] which has led to a substantial number of patients still not realising the maximum benefit of their treatment, frequent hospital admissions and even avoidable deaths.[3,4] In addition, there continues to exist a significant associated economic burden.[5-7] Previously, we described the role connected devices could play in improving asthma and COPD care, including the requirements for mass adoption, and introduced our inhaler with fully embedded connectivity, the eMDI™, which is designed to address the needs of multiple stakeholders.

In our estimation, the coming years will see a broad introduction of connected devices into asthma and COPD care, following a stepwise approach to meet the requirements for mass adoption. As an example, new devices should, in general, not present any significant changes to the status quo and, in the specific case of connected inhalers for asthma and COPD, new designs should be based on existing forms and function similar to conventional "press-and-breathe" metered dose inhalers (MDIs).[1]

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Nevertheless, the mid- and long-term future of connected asthma and COPD care remains shrouded by a high degree of uncertainty, as key technology and market

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developments continue to evolve. One particular challenge is intersection of the rapid pace of technological advancement and change within the electronics sector and the very conservative and change-sceptical pharma industry. This article employs a simplified scenario analysis to provide insights into the future of connected asthma and COPD care in the US and Europe[8] and will, on that basis, also provide a perspective on potential developments of connected care in emerging markets like India, China and South America.

KEY ELEMENTS CONSTITUTING CONNECTED ASTHMA & COPD CARE

A scenario analysis is generally based on three key steps:

- Key elements describing the field of interest are defined.
- Potential future developments are evaluated.
- The various developments of different elements are combined to define consistent scenarios.[9]

When it comes to connected asthma and COPD care the key elements to consider are:

- Developments in device technology
- Developments in the technology of the platform solution, which encompasses a mobile front-end, cloud-enabled services and a database.
- That the patient point of contact, taken in terms of decision power over drug and regime, might change as smart technology begins to prevail.
- That a sound business model for connected asthma and COPD care is not yet fully defined.[1]

This article will focus on these four key elements. However, other considerations could also have been classified as key. Examples include the supply chain to the patient, which might be shaken up due to the introduction of smart technology, and medications being part of connected care platforms, as embedded devices will probably be introduced to controller medication first and rolled out to rescue medication later.

LIKELY DEVELOPMENT OF DEVICE TECHNOLOGY

The electronics becoming more intrinsically embedded has proven to be a key short-term development since this design approach facilitates devices that are intuitive for patients to operate, whilst offering increased data quality and greater marketing appeal compared with add-on devices.[1,10] Short-term, it is predicted that devices will be focused merely on tracking patient usage with rather simple sensor technology, for example electrical switches. This offers cost advantages on the one hand and limited changes to the status quo on the other, prompting broad patient adoption. Additional reimbursement on a wide scale is seen unlikely in that time scale.

Based on the experience of market players within the connected health device space, adding advanced sensors to track technique, such as inhalation flow, next to usage patterns is the next logical step. Examples of advanced sensor technology could include absolute and differential pressure sensors or accelerometers.

Long-term (i.e. more than ten years hence), three additional developments will likely shape the design of connected inhalers:

- On the electronic side, more electronic components, such as capacitors, will be directly printed onto flexible substrates, substituting conventional printed circuit boards (PCBs) with surface-mounted components.[11] Examples for components already being produced in a comparable fashion are high frequency (HF) and ultra-high frequency (UHF) radio-frequency identification (RFID) tags.[11]
- On the connectivity side, we expect new technologies offering direct device-to-cloud connectivity to substitute Bluetooth low energy (BLE) technology, as by then they should offer an improved patient onboarding experience and lower dependencies on third party devices, such as smartphones. Out of the competing technologies, e.g. Sigfox, Zigbee and NB-IoT, from today's perspective NB-IoT seems the most likely "winner", especially due to its roll-out being achievable in a rather lean fashion.
- On the overall device architecture side, the most significant change can be assumed. Comparable with electric cars, where so-called purpose-designed cars offer advantages over conversion-designed cars, connected devices will likely be designed around their electronic and connectivity features, for example offering active mechanisms to regulate the flow-rate in a dynamic fashion.

LIKELY DEVELOPMENT OF PLATFORM SOLUTION

In terms of the platform solution, it is anticipated that further optimisation of the user interface (UI), in terms of usability, will occur as the key-short term development. This is in line with larger scale studies being conducted by leading platform solution players utilising patient feedback for product refinement.

Mid-term, three likely developments can be expected:

- Platform solutions will be increasingly used to predict certain patient conditions, for example asthma attacks. Rescue inhaler usage could for example be used as a predictor of future severe exacerbations.[12]
- Applications will be more customised to specific patient needs. Taking, for example, the dose-reminder logic, rather than using a single approach across an entire patient population, we could see the use of different algorithms for different patient populations or an algorithm that can utilise harvested behavioural information to tailor itself to the needs of each individual patient.[13] This should lead to an increase in the average efficacy of connected care.
- Furthermore, there will be increased data integration between competing and adjacent systems. This will be required to cope with circumstances such as a patient who uses multiple inhalers from different pharmaceutical companies, each having its own separate software component, in parallel.[14] Additionally this will allow for connected monitoring systems, such as a spirometer, being added to connected care platforms.

Looking beyond that, platform solutions will likely control potentially existing active device functions and will offer dynamic dosage regimes as well as drug choice support to patients.

LIKELY DEVELOPMENT OF THE PATIENT POINT OF CONTACT

Physicians, partly in combination with other healthcare providers (HCPs), will continue to be the main point of contact for the patient, and make the decisions regarding drug and treatment regime, in the short-term. Access to data from connected care platforms can support both

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HCPs and patients with making informed decisions. Mid-term, we expect at least the perception of the benefits by the patient to change in line with the increased application and platform solution functionality. Long-term, the platform solutions could become the main point of contact and could make decisions on the regime and partly on the drug to be used by a specific patient. In that state, the physician would rather be in a monitoring and gatekeeper role – at least after the initial onboarding. Other players, such as telehealth centres, could foster that development, as they can combine distant patient monitoring and the option for human, non-technology driven intervention.

LIKELY DEVELOPMENT OF UNDERLYING BUSINESS MODEL

Short-term, the business model for connected asthma and COPD care will probably be driven by improved sales seen by the pharma companies introducing these systems, due to increased patient adherence, even taking into account that this model is subject to some uncertainties.[1] In exceptional cases, we expect to see the costs being directly funded by increased reimbursement. The UK NHS has already started the reimbursement of selected applications via its "Innovation and Technology Tariff"[15] and in Germany individual, tech-orientated insurance companies might fund specific connected care systems via specific selective contracts, called Selektivverträgen.

Mid-term, at least a medium probability exists that the majority of payers will move to outcome-based reimbursement, therefore demanding sufficient patient compliance, which in turn can be boosted by connected care. A potential for pharma companies to capture increased reimbursement on a broad basis prevails long-term, as connected care systems by then should offer significant additional value, even taking over some of the tasks traditionally performed by physicians.

RESULTING FUTURE SCENARIOS OF ASTHMA AND COPD CARE IN THE EU AND US

The discussed developments can be combined to potential short-, mid- and long-term scenarios of connected asthma and COPD care in the US and EU. Table 1 summarises these scenarios along the defined key elements and compares them to the status quo. To summarise further:

- Short-term: rather simple embedded devices will likely replace add-on devices. This will be funded by rising sales due to increased adherence and will lead to classical patient point-of-contact models prevailing.
- Mid-term: technique monitoring and patient-state prediction functions will likely be added to the platforms, partly to cope with increased pressure from the payers via outcome-based reimbursement models.
- Long-term: purpose designed devices driven by advanced platform technology offer the potential for pharmaceutical companies to shape the supply chain and the patient point of contact, capturing increased reimbursement in the process.

Key Element	Status Quo	Short-Term Scenario	Mid-Term Scenario	Long-Term Scenario
Device Technology	Passive add-on devices tracking usage using simple sensors, standard electronics and BLE	Passive embedded devices tracking usage using simple sensors, standard electronics and BLE	Passive embedded devices tracking usage and technique using advanced sensors, standard electronics and BLE	Purpose-designed, active devices tracking usage and technique using advanced sensors, printed electronics and post-BLE technology
Platform Technology	Non-patient customised, simple platform solution encompassing reminders and data display with limited integration capability with competing and adjacent systems	Non-patient customised, usability optimised platform solution encompassing reminders and data display with limited integration capability with competing and adjacent systems	Patient customised, usability optimised platform solution encompassing prediction, technique, reminders and data display with increased integration capability with competing and adjacent systems	Patient customised, usability optimised platform solution encompassing control of active device functions, dynamic dosage regimes, drug choice support, prediction, technique, reminders and data display with full integration capability with competing and adjacent systems
Patient Point of Contact	Physician is main point of contact and decision maker on drug and regime, app perceived as support tool	Physician is main point of contact and decision maker on drug and regime (supported by data), app perceived as support tool, other players evolving	Physician is main point of contact and decision maker on drug and regime (supported by data), app perceived as equally important as physician, other players established	Platform solution (partly in connection with other players) is main point of contact, decision maker on regime and proposes drug, physician in monitoring/gate keeper role
Business Model	Diverse	Increased revenue due to increased adherence, partly increased reimbursement	Increased revenue due to increased adherence, reimbursement depending on level of compliance	Greater revenue due to better adherence, reimbursement depending on level of compliance but increased due to additional value created

Table 1: Future scenarios of asthma and COPD care in the EU and US.

POTENTIAL DEVELOPMENT OF ASTHMA AND COPD CARE IN EMERGING MARKETS

Whilst emerging markets are no less willing to adopt connectivity and tech-based solutions than the established US and EU markets, most will have issues when it comes to the cost of adopting such solutions. As such, it can be expected that uptake will be significantly slower in these markets, with the possible exception of small, specific pockets or demographics that are less sensitive to cost. When considering these markets, it is worth investigating the possibility of low-cost variations or applications of the technology in order to lay the groundwork for a future scale-up to the fully featured versions when the resources exist to support it.

H&T PRESSPART'S EMDI POWERED BY COHERO™

To address the ongoing issues of patient adherence in the area of asthma and COPD and to offer the "next step" device and platform technology, H&T Presspart and Cohero Health (New York, NY, US) formed a strategic device development and marketing partnership. As a result of this multi-year collaboration, the companies have created the first market-ready, fully embedded, intuitive connected MDI solution: H&T Presspart's eMDI™ powered by Cohero™ (Figure 1).[1]

H&T Presspart's eMDI powered by Cohero™ comprises the device and platform technology, which will likely be applied in the EU and the US short-term and captures early mid-term functionality.

The eMDI device's connective hardware and software are fully-embedded within the actuator design. The electronics detect the actuation of the inhaler and the patient's actuation technique with the aid of switches, adds a date/time stamp and shares the data wirelessly via BLE with a mobile phone application – the BreatheSmart® application from Cohero Health.

The application, and the respective back-end in turn, form a comprehensive respiratory disease management platform, which reminds patients to take their doses and displays the usage data to them, with the potential to share it with other stakeholders. The usability of the patient interface has been optimised in an iterative manner and has proven efficacy. BreatheSmart users demonstrated patient retention of 72%, a 55% increase in daily medication adherence and a 95% decline in rescue therapy. The BreatheSmart® platform also encompasses accurate clinical-grade lung function measurement via a mobile spirometer, as well as other clinically actionable digital biomarkers. The capability for data integration with other systems, such as electronic medical records (EMR) and contract research organisation (CRO) tools has been demonstrated.

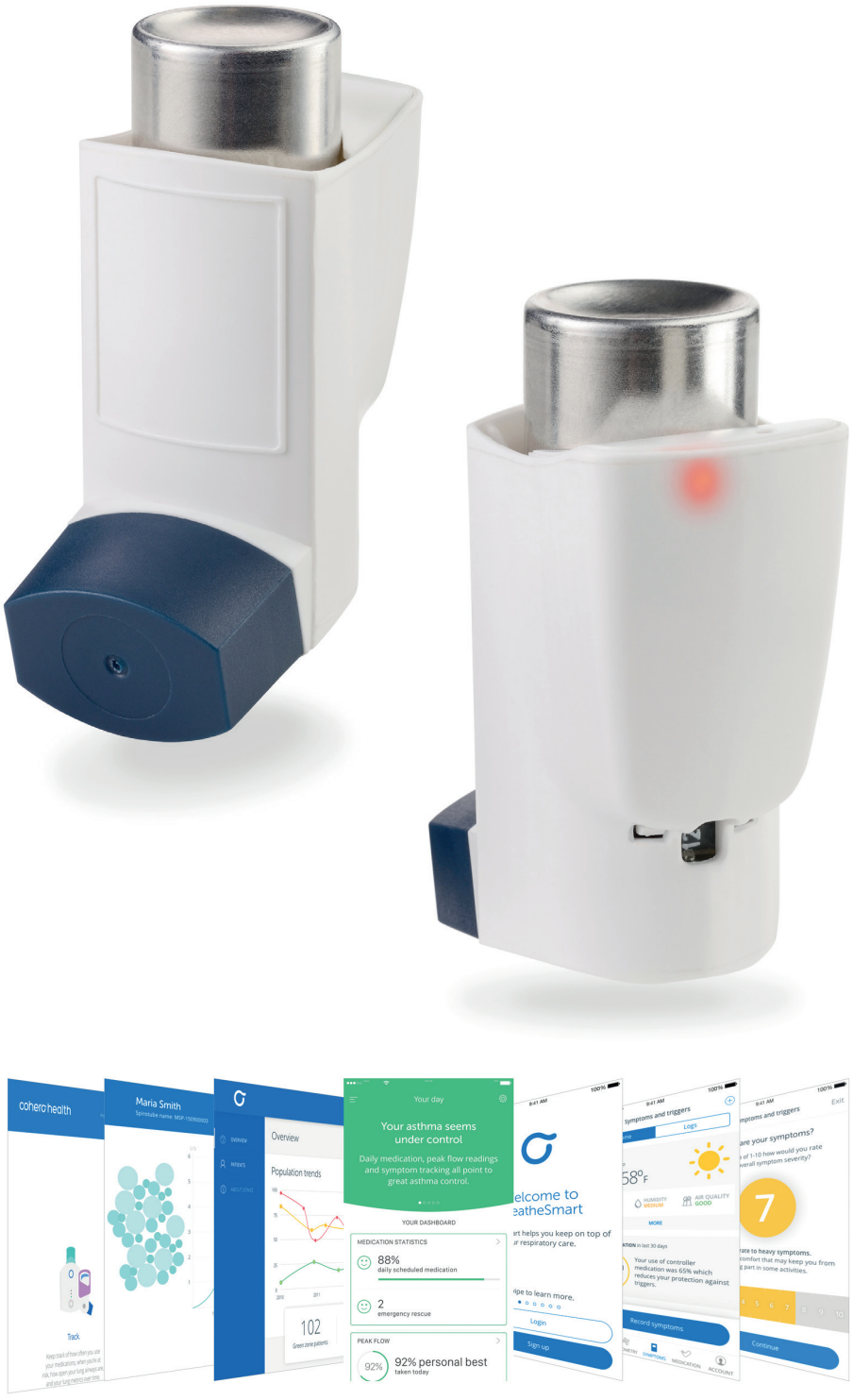

Figure 1: H&T Presspart's eMDI powered by Cohero™.

H&T PRESSPART'S QUANTUM DOSE INDICATOR AND APP

H&T Presspart's Quantum™ dose indicator and associated app represent a potential bridge solution into more advanced connected care models in emerging markets. The off-the-shelf Quantum dose indicator is an on-can MDI indicator solution, which ensures patients don't run out of medication. This is achieved with the aid of an arrow on the bottom of the can that indicates the remaining drug level.

The Quantum dose indicator app can be used to read this arrow almost automatically and thereby track the device usage via combining the can fill-level data gathered during individual arrow readings (Figure 2). It is available for Android and iOS mobile platforms and includes dose and prescription refill reminders. Last but not least, the functionality of the Quantum dose indicator app can be incorporated into a comprehensive respiratory disease management platform, such as BreatheSmart®.[16]

In summary, Quantum is a significantly lower cost method of capturing some of the functionality of a fully embedded system, offering a high differentiation potential for pharma companies in emerging markets.

CONCLUSION

The future of connected asthma and COPD care will likely unfold in a stepwise manner. Device and platform functionality, such as technique detection and patient state prediction, will probably be added over time allowing the pharmaceutical players to shape the patient interface and thus increase potential reimbursement value. With its eMDI powered by Cohero™, H&T Presspart has created a product which represents the logical next step on this journey, especially as it embeds the electronics into the device at a low cost.

Furthermore, H&T Presspart's Quantum dose indicator and its companion app can be implemented as a meaningful bridge solution to these advanced connected care models in emerging markets.

ABOUT THE COMPANY

H&T Presspart offers pharmaceutical customers high-precision injection moulded plastic components and deep drawn metal cans for respiratory drug delivery systems. The company has more than 45 years' experience and a worldwide reputation for competence, quality and innovation in the pharmaceutical and other industrial sectors. H&T Presspart Inhalation Product Technology Centre (IPTC) supports new product developments and strategic initiatives with its customers. Founded in 1970 and acquired by the Heitkamp and Thumann group in 2002, H&T Presspart has three European manufacturing sites in Germany, Spain and the UK, with sales offices in China, India, South America and the US.

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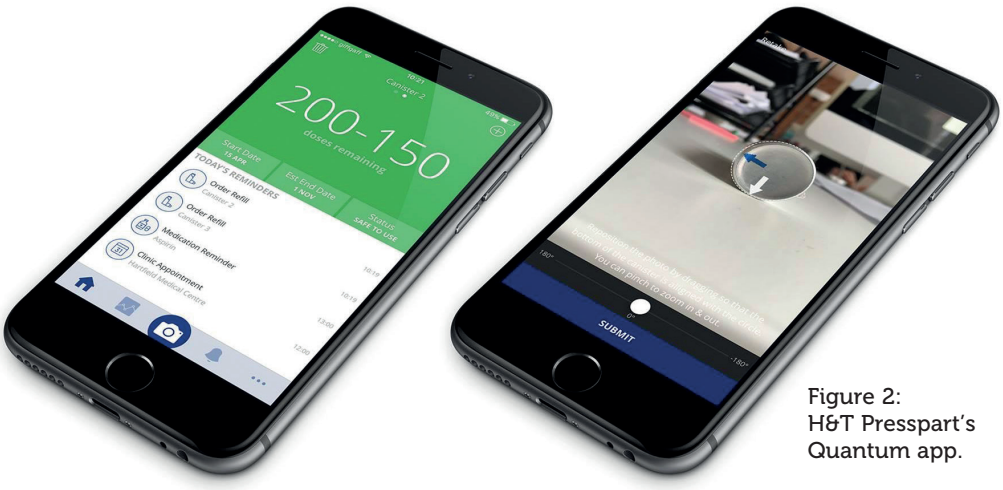

Figure 2: H&T Presspart's Quantum app.

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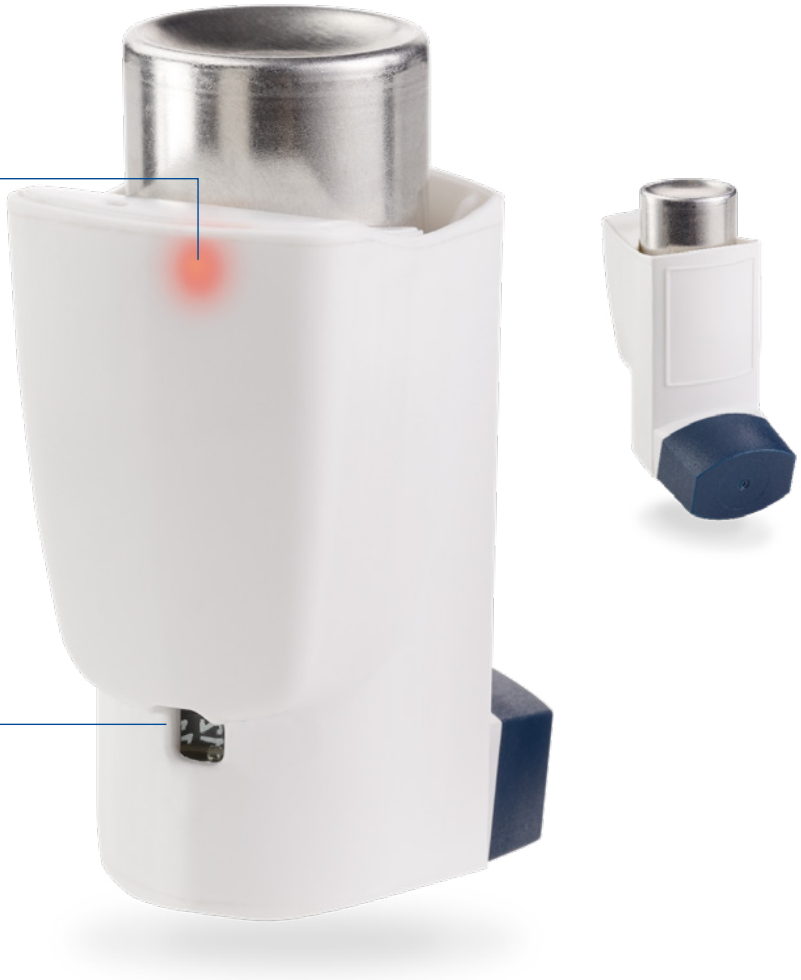
eMDI
powered by cohero

Smartphone app connectivity to allow real-time tracking and care management

Mechanical Dose Counter



Introducing the next generation MDI

H&T Presspart are pleased to introduce the first market-ready, fully-embedded, intuitive and connected metered dose inhaler (eMDI™) established to optimize care of patients ensuring from asthma and COPD.

The eMDI™ integrates seamlessly with BreatheSmart from Cohero Health, the only respiratory disease management platform that enables tracking of both controller and rescue medications, along with clinically accurate lung function measurement, in real-time.

For more information contact H&T Presspart:

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