Evolution or Revolution to Address Patient, Healthcare Professional and Payer Inhalation Device Needs

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Summary
3M estimates that the market for Dry Powder Inhaler (DPI) and Metered Dose Inhaler (MDI) products is worth approximately $40bn with around $6.5bn available for Contract Development and Manufacturing. This market is to primarily treat Asthma and Chronic Obstructive Pulmonary Disease (COPD).

A study was conducted to understand the real needs of each of the key stakeholders of inhalation devices to determine whether continued evolution or a step change revolution is required to satisfy the changing requirements for inhalation drug delivery.

A range of methods were used to capture the voice of stakeholder groups. An initial multi-disciplinary workshop was conducted to capture an inside-out view of the issues. This was followed by a series of independently facilitated telephone interviews with a small group of key opinion leaders across the industry to gain an outside-in view. These initial studies helped us to structure further stakeholder sessions. A series of interviews were then conducted face to face and thorough web based questionnaires with patients; face to face with Healthcare Professionals; and through the telephone with Payers.

The results highlighted four trending areas within inhalation, two hygiene factors that must be considered and two added value areas that will help to differentiate the next generation product. These factors are: ***Low cost; Patient Centric; Electronic Integration; Green Medicine.***

This study shows that there are unmet needs within the inhalation device market. There is space for improvements through a patient-centric device, incorporating integrated electronics that can capture real world patient outcomes data.

Introduction

3M estimates that the market for Dry Powder Inhaler (DPI) and Metered Dose Inhaler (MDI) products is worth around $40bn with approximately $6.5bn available for Contract Development and Manufacturing outsourcing. This market primarily delivers medication to treat Asthma and Chronic Obstructive Pulmonary Disease (COPD).

DPI and MDI products have dominated the hand held inhalation market but each delivery method has its own strengths and weaknesses. Different molecules lend themselves to delivery through one method or the other and each appeal to Pharmaceutical Companies, Patients, Healthcare Professionals (HCP) and Payers in different ways. DPI and MDI devices have undergone evolution, such as the migration from Chlorofluorocarbon (CFC) to Hydrofluoroalkane (HFA), and through the introduction of dose counters to satisfy the needs of some of these groups.

Since 2008 and the global financial crisis the role of the Payers within healthcare has changed significantly. We have also seen the patent expiry of many blockbuster inhalation products which has also changed the pharmaceutical landscape, particularly with more generic companies developing inhalation products. These are significant changes that drive a change in stakeholder requirements - but what else has changed and how will this affect the requirements for the next generation inhaler product?

The objective of this study was to understand the real needs of each of the key stakeholders of inhalation devices to determine whether continued evolution or a step change revolution is required to satisfy the changing requirements for inhalation drug delivery. This research should result in insights that help to clearly define the purpose of any new device development.

Method

A range of methods was used to capture the voice of the different stakeholder groups.

Multi-disciplinary workshop: 20 experienced 3M inhalation experts representing a cross section of the business were included in a workshop. The facilitated session considered the key stakeholders in inhalation such as Pharma, Payers, Clinicians etc. and then explored the issues affecting each. These issues were developed by considering each stakeholder's perspective and asking questions around their pain points and how they solve these pains.

Interviews: A series of interviews was conducted, initially with a subset of experts across the stakeholders from both the UK and US healthcare markets. This was followed by focused interviews with Patients, HCPs and Payers.

16 UK patients were interviewed walking through each patients disease history, the role of medication in their lives, how they use inhalers, what they like about devices and discussion around ideal device features.

8 US and 8 UK Healthcare Professionals were interviewed, initially finding out about their experience with Asthma and COPD and patient therapy, details of the care pathway, trends in the industry and how they see the future.

18 telephone interviews were conducted with payer experts from National Institute for Health and Care Excellence (NICE), Gemeinsame Bundesausschuss (G-BA), US state and private medical directors and Senior Pharmacy managers with budget responsibility.

Patient Web Portal: Over period of two weeks, 30 patients were engaged through the use of a web portal - 18 from the US and 12 from the UK suffering from Asthma and COPD across a range of ages. The portal had three sections, with the initial section capturing information on the participant demographics, condition history, disease management and previous experiences. The second explores inhaler usage, routines, an emotional evaluation, maintenance and accessories. The final section then considers device factors, features and how the devices are used.

Results

Multi-disciplinary workshop

Four key trends were identified; two were considered hygiene factors, while two were considered as trend drivers.

1. ***("Basic requirement/ Hygiene-factors") Low cost:*** Drive towards increasing discounts and generics for a lower health economic burden.
2. ***Patient Centric:*** More knowledgeable, discriminating purchasers. Patients ask more questions and access more information on treatments and devices. They are bombarded with information requests, resulting in a reluctance to share personal data. Increased focus on human factors is trying to address adherence and compliance issues.
3. ***Electronic Integration:*** The use of smart devices instead of clinical visits is reducing the burden of managing disease states. Even amongst the older generation systems are reducing the frequency of having to attend clinics in person. The systems are being established to drive wellbeing in society before higher cost interventions.
4. ***("Basic requirement/ Hygiene-factors") Green Medicine:*** Any solutions need to be sustainable and establish the right balance between environmental impact and patient wellbeing.

Key Opinion Leader Telephone Interviews - provide a more specific view of the trends within two categories.

1. ***Patient Centric***
   a. Keep it simple – "It should be something that you could give to a child and they can actually use it properly. So there's no training....it involves familiar concepts."
   b. Proven, better lung deposition
   c. Matching patient to treatment – "Everyone is different, (clinical) trials don't take that into account"
   d. Key issue is coordination
   e. Education - "Education will go head on with the underuse and poor compliance and misuse of the metered dose inhalers currently in the market"
   f. Remove the stigma – "The weak little boy with his asthma inhaler rarely is that held up as something that you want to be like."
2. ***Electronic Integration***
   a. Useful technology as a reminder– "Medicine has been behind the curve in using those devices to help people remember to do the things that they otherwise don't want to remember to do."
   b. Avoid potential pitfalls of technology – "Not just for the sake of it!"

Patient Web Portal

30 participants took part in the web portal, 83% are non smokers with an even split between the UK and US. 86% of the participants had received training to use their inhaler, with all of them admitting to feeling confident in using their inhaler device correctly. This is in contrast to the video evidence supplied that showed almost all participants demonstrating inhaler misuse. In addition 68% of participants said they were comfortable using their inhaler in public. 42% of participants worry about not taking their medication, yet 82% of them admit to forgetting to take their medications on a regular basis. Despite this 80% still feel that they are getting the most out of their medication.

Participant feedback on inhaler features is shown in Figure 1, reinforcing previously understood need for compact, lightweight inhalers, but also a preference towards breath actuation and a reusable actuator body.

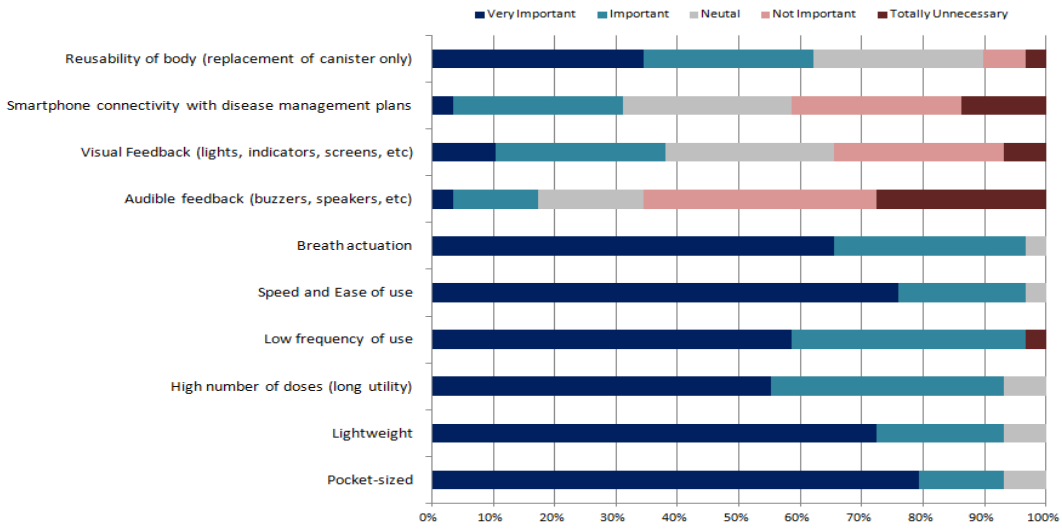

Figure 1: Quantitative feedback on possible inhaler feature-sets from patient web portal

Patient and Healthcare Professional (HCP) Interviews

The Patient and HCP interviews highlighted 5 areas for improvement with inhalers.

1. **Handling and usability**

   Patients struggle with several aspects of current device use, including dexterity and strength, the use sequence and techniques of dissimilar inhalers and controlling the breath profile. The devices are rarely intuitive to use.

"It needs to be simple and intuitive, basically idiot-proof! I've even seen nurses doing it wrong!" - Patient 2

"For me it's always nice not to have to spend as much time with teaching patients" - Doctor 8

2. **Improved feedback**

   Patients are seeking succinct feedback that they have successfully taken a dose. Visual and audible cues are all very important, however if these are not planned, they can result in misconstrued interpretations.

"You know you've taken it correctly because you can taste it. And it hits the back of your throat." - Patient 7

3. **Technique**

   Coordination and variation of breath profiles are widely recognised as issues with MDI devices. Figure 2 shows the patient variation in inhalation breath profiles using the same device.

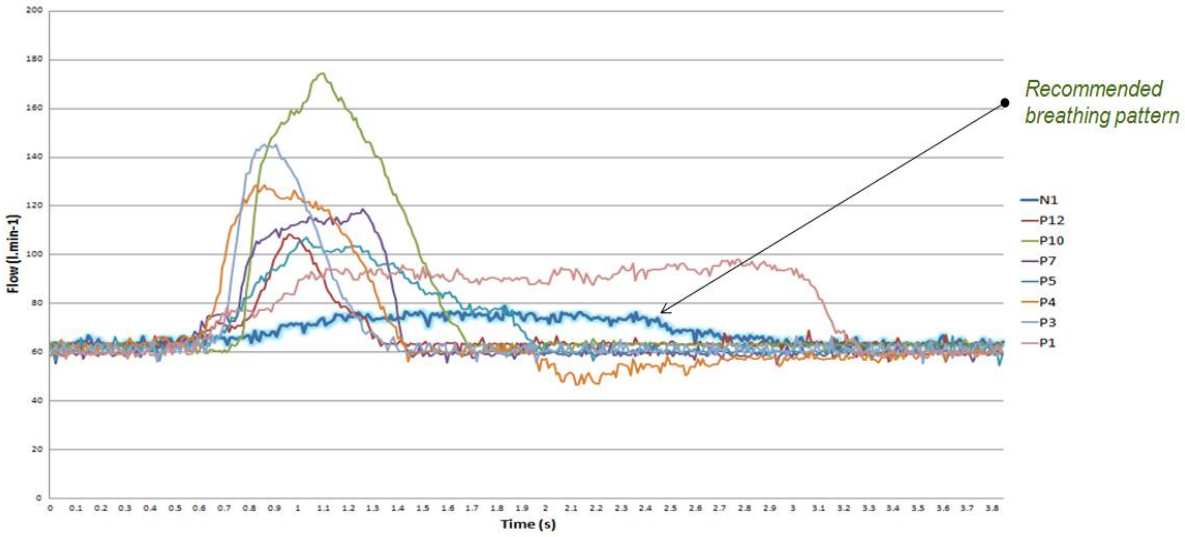

Figure 2: Participant MDI Inhalation Breath Profiles (N = Nurse; P = Patient)

4. **Condition management**

   Patients self-manage their condition, particularly Asthma patients. Some of this management is cost driven. It also appears that very little active monitoring takes place unless their condition becomes lifestyle limiting.

   Patients adopt different coping strategies to act as reminders to take their dose or to order more medication. The benefit of having a dose counter was broadly acknowledged as helping, but the indicator has to be clear and unambiguous, ideally with numbers and colours and not an arbitrary scale.

5. **Monitoring**

Very few of the patients interviewed had previously considered the potential for inhaler devices to have data logging or smart connectivity functionality. This resulted in a broad range of opinions over the value and potential features. This included contrasting opinions over data privacy.

HCP's had a divided view over the benefits of telemedicine features within inhalers. Some thought it would be good if it was used to help train and coach users to improve adherence. While others thought that collection of data around when the dose was taken would be useful.

"It would be more useful if the inhaler could tell you when they're using it." Nurse 2

"Something to coach you through and give feedback on how much was delivered, so it basically reinforces a patient's technique...I think this would enhance compliance with treatment." Doctor 8

Feedback on inhaler features from the face to face patient interviews is shown in Figure 3. This highlighted the need for better knowledge around dose – whether taken correctly or when to take it.

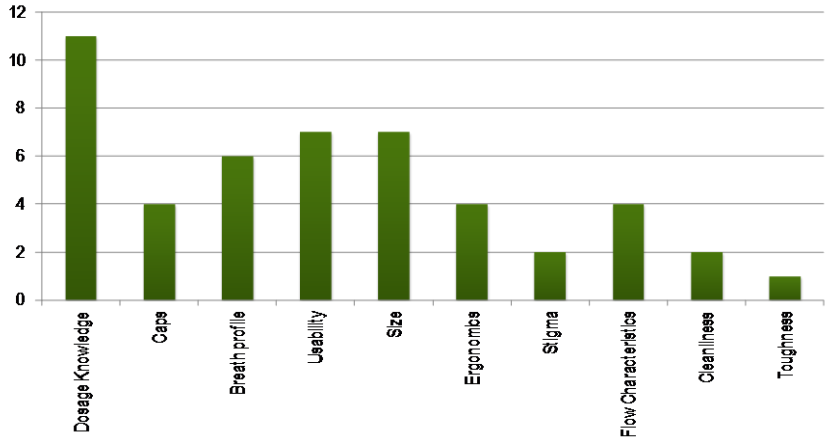

Figure 3: Qualitative feedback on possible inhaler feature-sets from patient interviews

Payer Interviews

The Payers discussed a strong change in this environment since the 2008 financial recession.

Across the UK, USA and Germany there has been a lot of restructuring and a drive to reduce healthcare costs. The UK restructured with Clinical Commissioning Groups (CCG), USA introduced the affordable care act, while the German G-BA also restructured. Across all of these areas there has been a greater focus on community and preventative care and a focus on linking pricing and reimbursement to proven patient outcomes.

"Once a low price is set – no amount of outcomes data will justify increasing it" Pharma 1
"Outcomes based contracts sound good, but you need the ability to track the data"

Discussion

The inside-out view and outside-in view of the inhalation market are very well aligned across each of the key stakeholders. Patient-centric and Electronic integration are validated as key trends within the industry. Cost was a major issue for the Payers, but in the shape of improved patient outcomes. This approach is seen as a more effective way of reducing costs across healthcare systems.

Patient-centric developments were reinforced through the need to have a simple intuitive device that allowed patient to patient variation to be taken out of the drug delivery process. This is primarily based around normalising the patients' breath profile through the device. The device should also reinforce the correct behaviour through feedback.

Electronic integration has mixed views from across the Patient, Healthcare Professional and Payer stakeholders. Where it does appear to find a home is in trying to capture real world data to confirm that improved patient outcomes are being achieved, allowing a higher level of reimbursement to be acheived.

Conclusion

Asthma and COPD continue to grow in prevalence and continue to be a significant burden to global healthcare systems. It is widely recognised that getting patients to take their medication at the right times and to take their medication effectively will improve patient outcomes and reduce more expensive medical interventions.

We have shown that there are unmet needs within the inhalation device market. There is space for improvements through a patient-centric device, incorporating integrated electronics that can capture real world patient outcomes.