MOVING TOWARD PATIENT-PREFERRED NASAL DRUG DELIVERY SYSTEMS

Today's patients are increasingly better informed and more opinionated about their treatment options and product preferences. With 400 million people worldwide suffering from allergic rhinitis, which includes hay fever and allergies to things such as mould, plants, dust and animal dander, demand for alternatives to aqueous sprays is growing. Here, Louise Righton, MSc, Global Market Development Manager, and Les Harrison, PhD, Preclinical & Clinical Manager, both of 3M Drug Delivery Systems Division, describe how providing patients with new, more preferred inhalation drug delivery devices is one way that pharmaceutical companies can improve compliance and increase success in this changing arena. They also review recent research highlighting patient preferences in device design and user experience for a nasal MDI.

With an estimated 400 million allergic rhinitis sufferers worldwide, the market for topical nasal sprays to treat this condition is significant.[1] The market for nasal corticosteroids, the leading therapy type, is worth some US$2.5 billion (£1.6 billion), with the leading brands achieving blockbuster status.[2]

However, these sales figures do not necessarily indicate satisfied customers. Since CFC propellants were phased out in the 1990s, aqueous pump sprays have been the primary delivery mechanism for nasal corticosteroids (Figure 1), and patients report that using these sprays can be unpleasant, and inconvenient. For example, drug formulation frequently drips down the back of the throat (post-nasal drip), not only causing an uncomfortable sensation, but also a bad aftertaste. Additionally, the

Figure 1: A selection of currently marketed aqueous pump sprays.

(Boots Hayfever Relief Nasal Spray is a trademark of The Boots Company plc; Nasacort® Allergy Nasal Spray is a registered trademark of sanofi aventis; Flixonase Allergy™ Nasal Spray is a registered trademark of GlaxoSmithKline; Nasonex® is a trademark of Merck & Co; Beconase® Hayfever Relief for Adults is a registered trademark of GlaxoSmithKline; Rhinolast® Nasal Spray is a registered trademark of Meda Pharmaceuticals Ltd.)

Ms Louise Righton
Global Market Development Manager
T: +44 1509 613626
E: lrighton@mmm.com

Dr Les Harrison
Preclinical & Clinical Manager
T: +44 1509 613626
E:liharrison@mmm.com

3M Drug Delivery Systems Division
3M House
Morely Street
Loughborough
Leicestershire, LE11 1EP
United Kingdom

www.3m.com/dds

liquid can run back out of the nose, embarrassing patients and reducing the retained dose. The sales figures for this category, therefore, should be viewed as a testament to the effect of allergic rhinitis on quality-of-life, meaning that sufferers' desire for treatment is so strong that they will tolerate uncomfortable products in the name of relief.[3]

Insights like this highlight the need for pharmaceutical companies to develop new, better solutions for allergic rhinitis. In a competitive marketplace, major opportunities exist for those who can improve the user experience with an innovative drug delivery device. Indeed, pharmaceutical leaders are increasingly focusing on and considering the user experience, as a patient-driven marketplace demands increased attention to these factors. Over the coming years, companies must develop solutions for drug delivery that are efficient and user friendly in order to build patient preference.

In the allergic rhinitis market, a nasal pressurised Metered Dose Inhaler (pMDI) device (Figure 2) represents one helpful solution to the problems associated with aqueous sprays. This device allows the medication to be administered as a quickly evaporating, no-drip spray. Furthermore, patient-friendly features such as dose counters and ergonomic designs can help further differentiate a product from competitors. In this patient-driven environment, the addition of features like these can help build patient preference and assist in the regulatory process. This article will review research recently conducted that highlights patient preferences in device design and user experience for a nasal MDI.

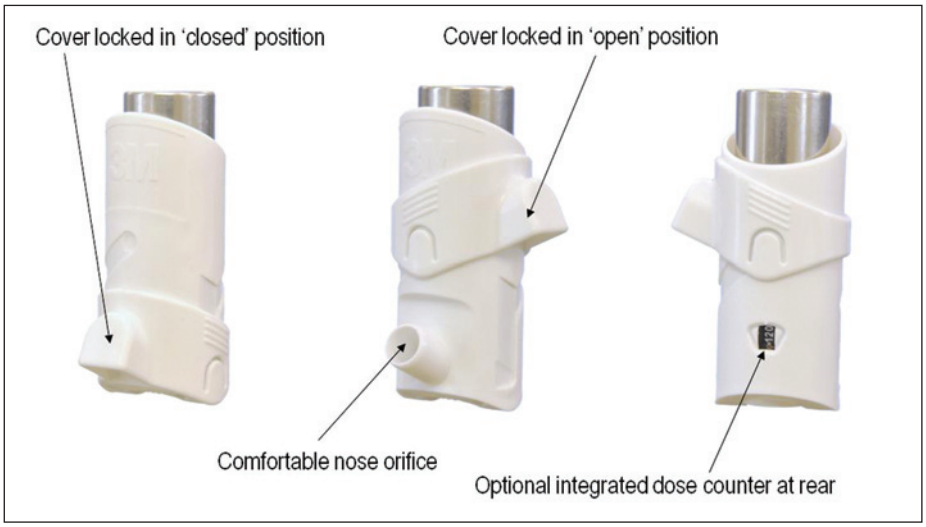

Figure 2: The 3M Nasal MDI from 3M Drug Delivery Systems.

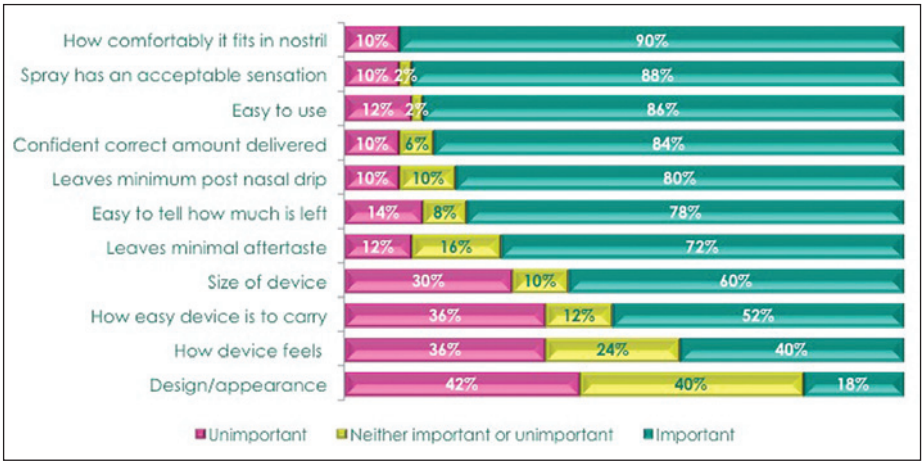

Figure 3: Ranking of importance of characteristics when using a nasal spray.[4]

UNDERSTANDING KEY DIFFERENTIATORS FOR PATIENTS

In an effort to understand the needs of allergic rhinitis sufferers better, 3M Drug Delivery Systems recently conducted a clinical research study comparing a new nasal MDI device with existing aqueous pump spray devices. The patient acceptance research was conducted with adult users of nasal spray devices. Study participants used the new nasal MDI device, and compared it with their experiences of using currently available pump spray devices. Their responses were collected in interviews designed to highlight the holistic patient experience of using nasal devices, and to gauge what considerations are most important to patients when considering their choices in nasal sprays.

To gain these insights, an open-label study in fifty participants was conducted in which responses to written questions were used to evaluate subject preference for a new nasal aerosol device. In parts one and two of the study, researchers first asked subjects for their initial impressions of the new MDI design in a questionnaire format. In the third part of the study, subjects were asked to read application instructions for the inhaler and apply one placebo aerosol spray from a prototype nasal aerosol device to one nostril, and a second placebo aerosol spray from the same device to the other nostril. Participants then completed a questionnaire comparing the prototype device with conventional nasal pump sprays. With this data, researchers gathered a picture of subjects' overall perceptions of the nasal MDI device; their experiences in administering the aerosol up the nose; the device's ergonomics, size, feel and fit; and their overall evaluation of the device in comparison with their current aqueous pump spray device. In the final part, to put these opinions into perspective, researchers also gathered data on the importance users placed on various attributes of a nasal device.

"INSIGHTS LIKE THIS HIGHLIGHT THE NEED FOR PHARMACEUTICAL COMPANIES TO DEVELOP NEW, BETTER SOLUTIONS FOR ALLERGIC RHINITIS. IN A COMPETITIVE MARKETPLACE, MAJOR OPPORTUNITIES EXIST FOR THOSE WHO CAN IMPROVE THE USER EXPERIENCE WITH AN INNOVATIVE DRUG DELIVERY DEVICE"

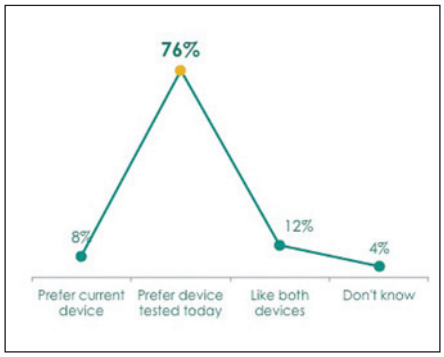

Figure 4: More than three quarters of subjects preferred the Nasal MDI over their current pump spray device.[4]

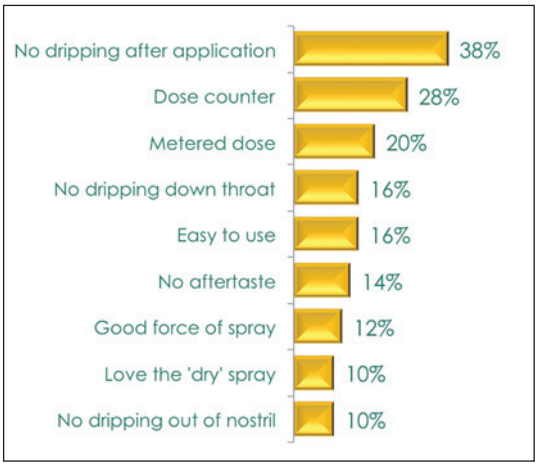

Figure 5: Reasons for preferring the 3M Nasal MDI over aqueous pump sprays.[4]

EMPHASIS ON COMFORT

The study found that comfort (a halo of attributes including comfort in nose and spray sensation) is the most important consideration when buying and using a nasal spray. 90% of subjects stated that how comfortably a device fits in the nostril was a key factor, and 88% stated an acceptable spray sensation was most important (see Figure 3).[4]

Following closely in importance after comfort were factors related to the user experience, including ease of use, confidence in the amount of drug delivered, minimisation of post-nasal drip, and how easy it is to tell how much medication is left in the device.

Lower-ranked factors included size and portability concerns, as well as factors related to a device's appearance and feel. Whilst subjects may not have ranked these concerns as highly as those related to comfort, ease of use, and good delivery, it is important to keep in mind that they remain key considerations given that allergic rhinitis devices are often used outside of the home—or would be if patients felt comfortable doing so. Any device intended to treat a condition triggered by pollen or pollution should be designed with portability in mind to encourage patients to keep it with them outdoors.

IMPRESSIONS UPON HANDLING AND USE

In the evaluation of impressions of the prototype nasal MDI, subjects were given several minutes to handle the device before use. Initial responses to the inhaler at this time were positive, with participants giving unprompted responses praising the secure, attached cap, the convenient dose counter and the fit of the device in the hand.

Following their initial handling assessment of the device, subjects were given instructions for use of the device containing placebo formulation. Upon use, subjects rated the device highly with a mean score of 8.1 on a scale of one to 10. This rating was attributed to the pleasant and comfortable experience of using the inhaler, with participants citing its ease of use, lack of dripping after application and metered dose as top reasons for their ratings. When asked to rate how easy the device was to use on a scale of one to 10, participants gave the inhaler a mean score of nine.

"IN AN EFFORT TO UNDERSTAND THE NEEDS OF ALLERGIC RHINITIS SUFFERERS BETTER, 3M DRUG DELIVERY SYSTEMS RECENTLY CONDUCTED A CLINICAL RESEARCH STUDY COMPARING A NEW NASAL MDI DEVICE WITH EXISTING AQUEOUS PUMP SPRAY DEVICES"

Following completion of the device test, when asked to state a preference for either their current nasal pump spray device or the new nasal MDI, more than three quarters of subjects stated a preference for the new nasal MDI (see Figure 4).[4]

INNOVATIONS FOR PATIENT CONFIDENCE

An important advantage of a nasal MDI over an aqueous pump spray is the inherent metered dose. In the research, subjects who used the nasal MDI assigned a mean importance of 8.8 on a scale of one to 10 for the fact that the inhaler delivered one set dose per spray, regardless of how hard they pressed the button, compared with a force-dependent aqueous pump spray, for which the dosage can vary significantly (Figure 5).[4]

As noted above, the nasal MDI used in this research also incorporated a dose counter, which was similarly well received by users (Figure 6). By looking at the dose counter before and after using the device, patients receive a visual confirmation that the dose has been delivered, and they no longer have to wonder about how much medication is left in the device or whether they should replace it. Benefits like this help patients feel more secure using a device, as reflected by the high score this feature was given in the research.

Among these subjects, the dose counter and metered dose features were cited as top reasons for preferring the device verses their current nasal pump spray, along with the fact that the MDI delivers a no-drip spray, which does not run back out from the nose or drip down the back of the throat after application (Figure 5).

ARE YOU PROVIDING YOUR CUSTOMERS WITH EVERYTHING THEY NEED TO "BUY IN"?

In today's digital world, patients have ready access to product information, reviews and forums, and those who are dissatisfied with the products they depend on often research alternatives independently before meeting with their health care professional. In this environment, pharmaceutical companies must be more mindful than ever before to develop treatments that keep user-friendliness at the forefront. Products that disregard these factors, or that do not offer useful differentiation from the field of competitors, are easily overlooked in a patient-influenced prescribing process.

The research summarised in this article details the top issues of concern for users of nasal treatments for allergic rhinitis, and clearly demonstrates the opportunity for a more patient-friendly solution than those that are currently being marketed, with over three quarters of patients preferring the 3M Nasal MDI compared with their current aqueous pump spray.[4] With a treatment solution that addresses patients' needs and wants—for ease of use, comfort, convenience and efficacy, pharmaceutical companies can gain buy-in from patients who are eager for new alternatives.

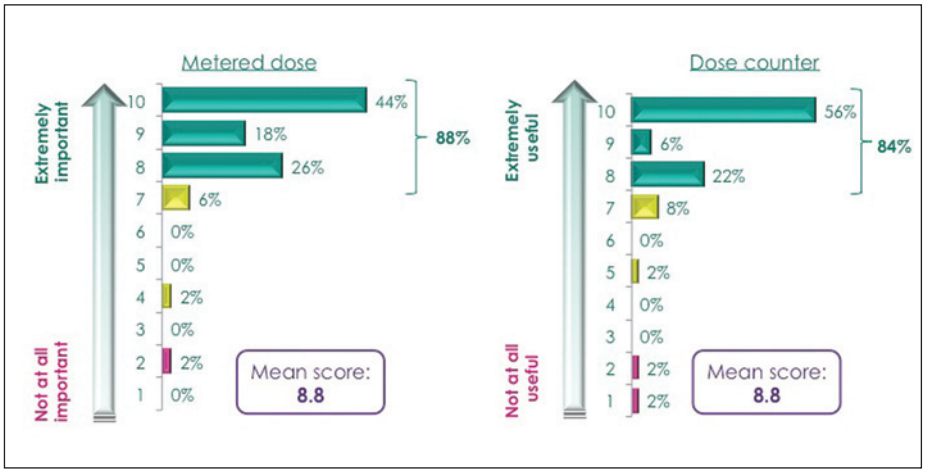

Figure 6: Assessment of metered-dose and dose-counting features of a nasal MDI.[4]

GETTING STARTED

Identifying what makes a device stand out for patients is not always a simple task. In efforts to develop new solutions, pharmaceutical companies should seek out technology development and manufacturing partners who are committed to understanding patients' needs and incorporating their voices into developing future technologies. With the development of any new drug product, especially a new delivery system, pharmaceutical companies must also always keep the practicalities of manufacturing in mind. By working with a partner that is committed to ensuring an efficient and cost-effective development and manufacturing process, while at the same time innovating to deliver patient-preferred solutions, companies can maximise the chances of success for their new nasal MDI product.

"AMONG THESE SUBJECTS, THE DOSE COUNTER AND METERED-DOSE FEATURES WERE CITED AS TOP REASONS FOR PREFERRING THE DEVICE VERSUS THEIR CURRENT NASAL PUMP SPRAY"

REFERENCES:

1. *"Global Surveillance, Prevention and Control of Chronic Respiratory Diseases: a Comprehensive Approach", World Health Organisation, Geneva, 2007.*
2. *"The Asthma, COPD & Allergy Market Outlook to 2016", Business Insights, May 2011.*
3. *Proprietary 3M patient research conducted in the US & UK, December 2009.*
4. *Proprietary 3M patient research conducted in the US, July 2012.*

3M DRUG DELIVERY SYSTEMS

INHALATION DEVICES

There are many reasons to choose 3M as your MDI partner. This is the one that counts.

3M's MDI devices are accurate, customizable, patient friendly, and ready to be integrated into your application.

3M's innovative dose counter and nasal inhalation systems provide a differentiating delivery method, giving our partners a competitive edge.

Through the development of intuitive patient-friendly innovations, 3M's MDI devices and components enable your treatments to stay on the cutting edge while making life better for patients. We offer:

- Leading edge devices ideal for aerosol delivery through the lungs or nasal cavity, for Asthma, COPD and Allergic Rhinitis.
- Technologies that meet growing market demand for patient-friendly devices such as nasal MDIs and dose counters.
- Products designed and developed with patients in mind, ensuring product differentiation, and resulting in a competitive advantage for our partners.

With a 50 year history of innovation and success in inhalation technology, 3M's MDI experts can help you gain a competitive advantage.

Make life better for patients today at **www.3M.com/pMDI**

US: (1) 800 643 8086
UK: (44) 1509 613626
ASIA: (65) 6450 8888

ENABLING YOUR SUCCESS

3M