USING MARKET RESEARCH TO CREATE A PRESERVATIVE-FREE MULTIDOSE EYEDROPPER

An ageing population, high computer and mobile device use and increasing pollution and allergies are all contributing to a greater global demand for eyedrops. At the same time, the move towards preservative-free formulations is driving the development of novel ophthalmic devices. Thomas Grinnan, Vice-President, Sales & Marketing, Healthcare, and Ralf Hergenröther, Product Line Manager, Healthcare Solutions, both of Silgan Dispensing Systems, explain how extensive market research and consumer testing led to the development of an eyedropper that meets patients' and physicians' needs for an easy-to-use device, which offers precise dosing and anti-microbial integrity.

Ophthalmic health is becoming an ever more significant issue due to factors such as the continued growth of urban populations, an ageing population and a rise in the levels of particulate matter in the air. In 2017, the global ophthalmic drug market revenue was US$24 billion (£19 billion).[1] By 2021, it's expected to be $28 billion, with retinal disorder, allergies, glaucoma and dry eye disease (DED) among the biggest categories fuelling the growth. Also driving market expansion is the fact that some of the diseases that require the use of eyedrops are chronic.

PRESERVATIVE-FREE PACKAGING

While ophthalmic medicines are traditionally packaged using preservatives, and primarily still are in the US, there is currently a push in Europe towards using preservative-free (PF) packaging, following research which suggested that preserved eye medications can be harmful to the eye. For example, one study[2] reported that, benzalkonium chloride (BAK), a preservative commonly used in eyedrops, has been associated with toxic effects such as "dry eye" and trabecular meshwork degeneration.

In response, European regulators now require special labelling for ophthalmic medications. Demand for PF medications is also driven by patients, who increasingly prefer natural, organic and PF products. Outside of Europe, preserved ophthalmic medications comprise the majority of the global market and are primarily delivered in small, multidose squeeze bottles.

In the US and beyond, a large portion of the global PF market currently uses single- or unit-dose packaging, which not only tends to be more expensive than bottles and overfilled for a single dose, but also difficult to use. PF multidose systems are a substantial improvement over these unit-dose packs.

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PATIENT NEEDS

Silgan Dispensing has built a reputation for expertise in PF dispensing and scaled manufacturing, as well as in-depth consumer insights and market research, enabling it to deliver innovative and customisable solutions to meet the needs of its clients. As a leading global supplier of highly engineered triggers, pumps, sprays and dispensing closure solutions, Silgan Dispensing products are seen every day in the home, health and beauty markets.

Silgan Dispensing's market research into the ophthalmic market revealed several trends: rising consumer preferences for natural, organic or PF products; the need for a more patient-friendly, PF, multidose packaging solution; and the global shift away from preservatives in ophthalmic medicines, particularly for chronic medications.

For most patients, standard eyedroppers also pose a challenge. Who among us hasn't missed their eye when trying to use one? Or who hasn't wondered whether the appropriate amount of medicine actually reached their eye? Using its market insight capabilities, Silgan Dispensing discovered that patients also want control, both in the amount of product dispensed and how it gets into their eyes. They want precision, so that they can be sure of how much product they are dispensing, and they want the ability to dispense only one drop at a time.

Figure 1: Iridya™ is Silgan Dispensing Systems' new preservative-free multidose eyedropper.

This need for precision was also confirmed by ophthalmologists, who requested more exact dosing for key diseases, such as glaucoma. Patients are also concerned with wasting medicine because of inadvertent overdosing due to dripping, jetting or streaming. And they want simple delivery to ensure the product actually makes it into their eyes.

> "A key attribute of Iridya™ is its strong anti-microbiological integrity, which was tested and proved by an independent laboratory."

THE DEVELOPMENT OF IRIDYA™

Silgan Dispensing coupled its market insights, engineering and design, and industry experience to create a ground-breaking solution that answers both the dosing concerns of ophthalmologists and the control desired by patients – Iridya™ (Figure 1).

Silgan Dispensing began the product development process by discussing unmet needs with ophthalmologists, learning that existing PF solutions were not meeting patient needs for best-in-class medical care. The company assembled engineering and design teams to develop initial designs and prototypes. Development teams also studied how to create a product that would be resilient and secure from microbial access, taking the unmet market needs into consideration. In this process, Silgan Dispensing was able to leverage its extensive expertise in designing, manufacturing and scaling medical devices for filling at high speed on customers' filling lines while ensuring antimicrobial integrity, utilising more than a decade of PF nasal device experience.

Silgan Dispensing then benchmarked the design against competitor devices on the market and tested its system in consumer focus groups. Both competitor benchmarking and consumer research confirmed that it was on the right track and provided valuable feedback to improve the design to address more unmet patient needs. The final result is the Iridya™ system, launched at CPhI Worldwide in Madrid in October 2018.

THE UNIQUE FEATURES OF IRIDYA™

Iridya™ is an eyedropper that improves on existing technology by combining advanced ergonomics and precise dispensing to ensure proper dosage, drop after drop. The device, which works for many formulations, provides an innovative solution for pharmaceutical partners, which may drive patient use and physician prescriptions.

Ergonomics and drop control

Iridya™ features a familiar, round, squeeze bottle design, but what makes it unique to the PF market is its elongated tip, which ensures greater accuracy when administering drops to the eye. Adding to the convenience for patients are the low actuation force and ergonomic grip on the overcap – features that are often important to older patients (Figures 2 and 3). Overall, the eyedropper's balanced system is easier to handle and

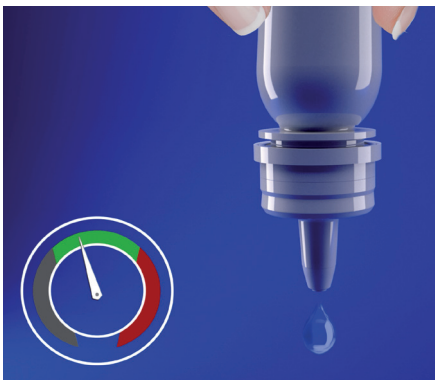

Figure 2: Iridya™ has a low actuation force.

Figure 3: The ergonomic grip on the overcap makes it easier for older patients to use.

provides patients with greater control when applying their drops.

Key factors in drop control are the device's Advanced Flow Control and NO-JET™ technologies. The Advanced Flow Control system ensures exceptional drop control for precise dosing down to the drop. The NO-JET™ technology helps to eliminate streaming or jetting, ensuring single doses drop after drop, even if the bottle is squeezed hard, throughout the life of the product.

Safety and Flexibility

A key attribute of Iridya™ is its strong anti-microbiological integrity, which was tested and proved by an independent laboratory. Formulations are protected from contamination by a novel barrier system at the tip and other mechanical features within the device, including a sterile air filter, air filter protection and a shut-off valve. These innovative features provide maximum protection, and the materials used are compliant with existing ophthalmic regulations. The system is sterilised via gamma irradiation, has no metal contact with fluid and does not use silver ions (Figure 4).

Because of the device's Advanced Flow Control, Iridya™ adapts to different formulation properties, and its standard configuration is compatible with a range of low- to high-viscosity formulations. It also meets new formulation trends like gels or combination formulations and, because one standard model fits a wide range of formulations, Iridya™ can save supply chain and administrative costs.

Lastly, due to its round, standard bottle shape and shallow design, Iridya™ is compatible with most sterile multidose eyedropper filling lines. The snap-on closure design and large bottle neck allow for fast, easy filling. Silgan Dispensing Systems is working with multiple filling sites and machine manufacturers to supply Iridya™ for automated filling of ophthalmic formulations.

HOW THE PF MULTIDOSE SYSTEM WORKS

Iridya™ works very much like a standard eyedropper squeeze bottle. When holding the bottle upside down, the user squeezes with thumb and finger. With this pressure, the formulation is pushed towards the outlet valve below the tip's orifice. Increasing pressure also compresses the spring-loaded

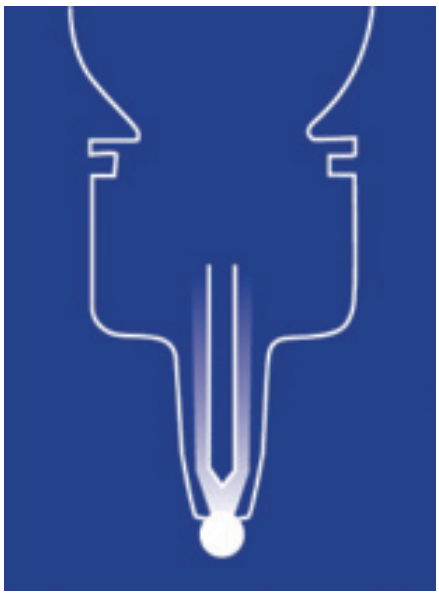

Figure 4: The innovative triple-barrier system inside the dropper provides strong microbiological safety and offers maximum protection of the formulation.

valve, allowing the formulation to flow. The valve closes immediately afterwards, as the squeeze force decreases, returning to its protected state. As liquid is forced out of the hermetically sealed system, air is also entering through the sterile air filter and back into the system for bottle venting. This innovative triple sealing and filtering technology prevents the liquid from flowing back into the system to keep the formulation contamination-free.

> "Users preferred the overall ergonomic feel and squeeze bottle familiarity of Iridya™ compared with all the solutions tested."

CONSUMER TESTING

During the development of Iridya™, the Silgan Dispensing team conducted consumer focus group testing to gauge the effectiveness of its design at addressing consumer needs, and how the design compared to the performance of other PF droppers on the market (Figure 5).

In Europe and America, the Silgan Dispensing team performed multiple consumer focus group studies,[3] with each session featuring the following elements:

- General discussion.
- Tactile testing, where participants provided feedback relative to the packaging as they physically examined and opened it.
- Experiential testing, where participants dispensed drops into their eyes using Iridya™ and gave feedback on control, aiming, force to actuate and ergonomics.

The results of the consumer testing showed that participants favoured Iridya™, with it outperforming other available PF eyedroppers in aiming control and ease, one drop control and force to actuate. Additionally, Iridya™ was the only dropper that did not jet or stream when squeezed with force and there was no panelling or warping of the bottle. Users preferred the

Figure 5: The bottles are designed with consumers in mind, with both white and transparent options available and using soft material and coloured overcaps.

overall ergonomic feel and squeeze bottle familiarity of Iridya™ compared with all the solutions tested.

CONCLUSION

Rising demand for patient-friendly PF eyedroppers drove the development of Iridya™. Consumer and market research were critical inputs to Silgan Dispensing's design and innovation process. Patients are looking for control – over both accurate dosing and how much product is dispensed. They want a device that helps them target the eye correctly, delivering an accurate dose, one drop after one drop, without wasted product. Physicians want an easy-to-use device with precise dosing and anti-microbial integrity.

Iridya™, Silgan Dispensing's new PF multidose eyedropper, solves the unmet needs of patients and the medical community by ensuring exceptional drop control and precise dosing for preservative-free medications, delivering a better patient experience and improved patient care. This new solution also affords pharmaceutical brands a new option that is compatible with most market formulations and has a validated sterilisation supply chain for device and bottle, making Iridya™ the ideal delivery system for both over-the-counter and prescription ophthalmic drugs.

ABOUT THE COMPANY

Silgan Dispensing is a leading global supplier of highly engineered drug delivery devices to major pharmaceutical companies in the healthcare market. With its breadth and depth of technology, consumer insights and manufacturing expertise, Silgan Dispensing provides innovative and customisable solutions that meet brand owners' needs. At the same time, it makes sure patients can easily and reliably dispense the right dose. Its meticulous approach to pharmaceutical dispensing enables it to give both brands and patients better results.

Silgan Dispensing believes that every dispenser should have its own DNA – the unique elements that make it function flawlessly with the medication inside it and the patient who is using it. Silgan Dispensing's state-of-the-art dispensing solutions can be customised down to the smallest component, ensuring a safe, effective and easy dosing experience.

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3. *Consumer focus group studies of Silgan Dispensing*

ABOUT THE AUTHORS

Thomas Grinnan, Vice-President, Sales & Marketing, Healthcare, Silgan Dispensing Systems, has worked in the pharmaceutical industry for more than 28 years as an executive, innovator, consultant and business development specialist. A biologist, he began his career in strategic consulting, working closely with pharmaceutical and medical device companies. After a long career at Westvaco, MeadWestvaco and Westrock's Healthcare and Patient Adherence packaging divisions, Mr Grinnan joined Silgan Dispensing Systems, a spin-off specialising in liquid dispensing solutions for nasal, topical and ophthalmic delivery. He received his BA from the University of Virginia (Charlottesville, VA, US) and his MBA from the University of North Carolina, Chapel Hill (NC, US).

Ralf Hergenröther, Product Line Manager for Silgan Dispensing Systems since 2007 has held various R&D, sales and marketing positions. As Global Marketing Lead in Healthcare Solutions, he actively promotes a large portfolio of dispensing products to pharmaceutical customers for nasal, ophthalmic, topical and otic applications. His main focus is to understand patient needs, regulatory concerns and packaging requirements, and to develop and market dispensing solutions that create a better experience for patients and doctors. Mr Hergenröther earned his MSc degree in engineering from FH Karlsruhe (Germany) and his business administration degree from HEC (France) in 2010.