Drug delivery technologies in the past have been based on relatively simple reformulations of existing pharmaceuticals. Growth is driven by technological innovation, additional therapeutic applications and increasing reliance on delivery devices to extend product life cycles. The past two decades have seen the development of multiple-technology platforms such as oral, inhaled, injectable, transmucosal and transdermal administration.

The growth of the biotechnology industry throughout the last decade has brought a wealth of bioengineered products to the market place. Therapeutic proteins and peptides, which offer significant treatment advances for patients with conditions including cancer, inflammatory diseases such as rheumatoid arthritis or psoriasis and autoimmune diseases such as multiple sclerosis. The development of these new and complex treatments presents new challenges for innovative drug delivery technologies and new opportunities for growth in this market.

Unlike conventional “smaller molecule” medicines, bioengineered proteins and peptides are relatively large and fragile molecules, which require injection delivery as they may be destroyed by the body’s digestive system if taken orally. Biologicals administered by traditional injection are driving the development of new drug delivery technologies, to enhance patient convenience and compliance, maximize therapeutic efficacy and optimize targeted drug delivery.1

Finding a New Way In

Novel approaches to drug delivery can boost patient compliance and have a significant impact on market acceptance. With medicated contact lenses and needleless shots, taking drugs has never been so easy.

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Patient non-compliance is a key issue in healthcare management, with a significant impact on treatment efficacy and benefits as well as the cost of the therapy.

The treatment of growth hormone deficiency is a key area wherein drug delivery devices play a crucial role in achieving simple, low pain administration of recombinant growth hormone to children and adults. This therapeutic area has a need for tailored delivery devices to meet the very specific needs of children, such as the autoinjector one.click, which allows automatic needle insertion and delivery of the recombinant growth hormone in one step keeping the needle out of sight before injection to reduce anxiety.

A needle-free device called cool.click reduces pain and anxiety for needle-phobic patients undergoing daily injections. This device has a disposable clear plastic nozzle instead of a needle. Growth hormone is administered by holding the device against the skin and pressing the release button. A spring in the device pushes the growth hormone through a small opening in the nozzle at high speed, enabling the drug to penetrate the skin. Shown to be bioequivalent to a traditional syringe with a needle, the needle-free device offers improved patient comfort.

There is room for a variety of patient-friendly devices in key therapeutic areas to increase patient ease of use and compliance. This is of particular importance in, for example, fertility treatment. Compared to the treatment of chronic growth hormone deficiency, which lasts many years, fertility treatment is short-term and patients — even though highly motivated — are usually inexperienced with injections. They demand a device that is easy-to-use, which takes little training to use.

SEPA (Soft Enhancement of Percutaneous Absorption) technology has been developed by the MacroChem Corporation, a Boston-based specialty pharmaceutical company. SEPA is a family of patented compounds that can, according to the company, enhance transdermal drug delivery by temporarily and reversibly disrupting the lipids in skin to make it permeable.

A 9-carbon member of the SEPA family — SEPA 0009 — to enhance the topical delivery of a variety of active pharmaceutical ingredients (APIs) has been developed and tested in 48 clinical trials conducted in Europe and the United States. A filing for regulatory approval for the first SEPA-enhanced product is expected by the company to occur in 2006. Opterone, a topical cream containing testosterone and SEPA 0009, is in clinical development to treat male hypogonadism. Topical testosterone delivery overcomes a number of problems, including first pass metabolism and the possible risk of liver damage by oral delivery and the aversion of some patients to needles. This cream formulation is said to have the added bonus of being able to deliver sustained levels of testosterone over a longer period of time when compared with a first generation gel formulation.

EcoNail, a lacquer formulation containing econazole and SEPA 0009, has also been developed to treat onychomycosis, a common nail disorder, and overcomes some of the disadvantages of existing antifungal drugs. In this formulation, SEPA 0009 promotes the release of econazole from the lacquer film. EcoNail is currently in clinical development. The company says that as chemical enhancement technologies develop the number of topical delivery treatments should increase.

The success of fertility treatment depends not only on the consistency of the drug, but also the accuracy with which it is administered. More precisely, the need for a simple device that is easy for patients to use, gives them confidence to self-inject and ultimately increases treatment compliance.

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Five years ago the fertility market was mainly dominated by gonadotropins delivered in conventional ampules or vials, requiring reconstitution of the medication prior to injection. Requiring many different steps to prepare an injection, patients undergoing short-term, highly emotional treatment often become fazed and anxious about the complexity of the administration of the drug.

Serono developed the Gonal-f Filled-by-Mass (FbM) prefilled pen to meet these needs. For patients, the device is simple; the pen is prefilled with the drug, ready-to-use and

has a dose checking system to prevent the patient from inadvertently loading more than the dose set on the dial. The benefits to patients of a prefilled pen are clear. An Australian patient undergoing fertility treatment was “a little frightened” about the thought of an injection and reconstituting the powder with the solution to load the syringe. She commented: “I am now so comfortable with the prefilled pen that I can even inject myself … I do not have to worry about air bubbles or any medication left in the syringe … For me, this is a great relief and makes the treatment more acceptable.” Her physician added that in his experience, when undertaking IVF, anything that reduces patient stress and increases confidence in the treatment is a significant advantage.

Extensive support services have helped to ensure the success of novel delivery systems. Intensive one-on-one nurse training programmes mean they can teach patients to correctly use the devices to aid compliance and the efficacy of the treatment. Further resources such as an online animated guide to self-injection, videos, injection maps and dose guidelines can also help patients and their nurses. The return on investment of this customer-need driven development is a very quick and significant market acceptance by physicians, nurses and patients in all regions. Competitive advantage and market share are no longer determined solely by state-of-the-art medication. In today’s market, the pharmaceutical and biotechnology industry must increasingly incorporate drug delivery systems that maximize patient ease-of-use into early development work. Patient compliance is integral to the effective treatment or management of a condition and the success of innovative delivery devices tailored to meet patient needs can tip the balance on treatment efficacy. Improved convenience through drug delivery devices will not only provide a competitive edge to the pharmaceutical companies, but can lead to better patient compliance and lower healthcare costs.

References

Patients suffering from eye ailments are often prescribed eyedrops to treat the illness or relieve discomfort. However, it has been found that as much as 95% of the medication administered in this manner could drain into the nasal cavity where it can flow through the blood stream to other organs, according to researchers at the Institute of Bioengineering in Singapore (IBN). Additionally, drug dosage to the eyes is often inconsistent and difficult to regulate as most of the drug is released in an initial burst of concentration.

To address some of these problems, Drs Edwin Chow and Yang Yi-Yan from IBN devised a simple method to medicate using a drug-loaded contact lens. This involved making a polymeric lens material that can be loaded with eye medication for ophthalmic drug delivery. Their novel one-step process involves incorporating drugs within a nanostructured polymer matrix using a microemulsion polymerization process.

Chow says the resulting material is compatible with human skin cells, as well as human corneal epithelial cells. “It is also permeable to gases such as oxygen and carbon dioxide, water and components of the tear fluid, so the material is suitable for biological and biomedical applications,” he explains. The drug delivery rate can be controlled by altering the size, concentration and structure of these polymeric nanoparticles while maintaining lens clarity, and the method can be tailored to different drugs while remaining effective for extended periods, according to Chow.

The researchers aim to apply this method to treat glaucoma, which accounts for 20% of blindness in Singapore. The IBN is currently looking for partners to help commercialize this product.

Source: www.ibn.a-star.edu.sg