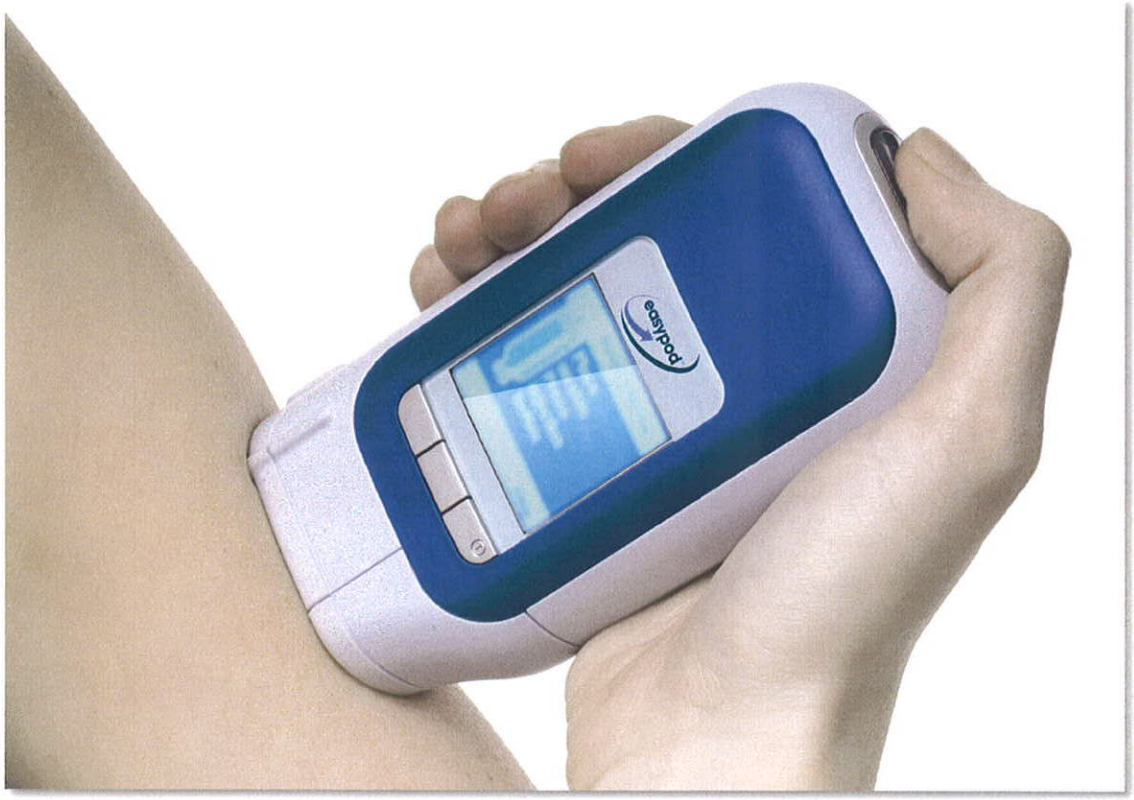

For publication

Project Title:	easypod ™ - advanced auto-injector device
Category:	Industrial Products
Client Company:	Merck Serono – Geneva
Design Consultancy:	PDD Group Ltd, London
Date of Entry:	24 May 2010

1. Executive Summary

In 2003 Merck Serono, a world leader in the field of biotechnology engaged PDD to design an auto-injector for its Growth Hormone (GH) therapy product Saizen®.

In what was a saturated and static market (in 2008 the market stabilized at around €2 billion)and with revenue being eroded by generic competition, Merck Serono wanted to increase market share by securing a higher percentage of new patients, encouraging patients on competitor therapies to change and by opening up new markets. With little difference in the efficacy of the drug existing between the GH therapy suppliers, differentiation had to be achieved by developing a device that would add value to the lives of patients and their families by making injection of the drug and adherence to the therapy easier.

Following research and development by PDD Group Ltd and detailed engineering and manufacturing by Flextronics Inc. the easypod™ device was launched in 2007. It is the first electro-mechanical device for subcutaneous injection of medicinal products. The patient and clinician benefits of this unique device have given Merck Serono clear differentiation in a market crowded with less sophisticated mechanical devices. Following its success with GH patients, it has now become a platform drug delivery device for Merck Serono; the Multiple Sclerosis (MS) version RebiSmart being launched in 2009.
Since the launch of the easypod™ in 2007 Merck Serono has:

- Increased GH global market share
- Increased access to global GH markets – a total of 39 countries including the US, Japan and China
- Increased revenue
- Improved living with GH therapy for thousands of patients worldwide

2. Project Overview

2.1 Outline of Project Brief

The brief was to identify opportunities to improve the Growth Hormone Therapy experience for all stakeholders; patients, families and clinicians so that a device could be developed that would give Merck Serono clear differentiation in a crowded and static market. The therapy can last several years so the aim was to increase market share by:

- Attracting a higher percentage of new patients
- Attracting patients to change from competitor therapies
- Opening up new markets

2.2 Description

Growth hormone therapy requires a daily injection of a patient specific dose, normally in a domestic environment, usually at bedtime, and administration can change from a parent injecting their child until such time as the child is able, or confident enough, to self administer the treatment.

2.3 Overview of Market

The growth hormone market had shown an average compound annual growth rate of 8% over the 5 years up to 2008, when the market stabilized at around €2,032 million.

Price erosion from generic suppliers was reducing revenues for the major suppliers like Novo Nordisk, Pfizer and Merck Serono.

Before easypod™, drug delivery was by traditional syringe or a range of manual pen injector devices.

2.4 Project Launch Date

European launch was in 2007.

2.5 Outline of Design Solution - 497 words

To understand the challenge of improving the GH therapy experience, PDD spent time with all stakeholders – doctors, nurses, adult patients, children and their parents. A therapy map was produced that covered all aspects of the process and highlighted the practical as well as emotional issues.

It was evident that the therapy can put enormous strain on the relationship between the parent and their child. Some parents were so stressed by the therapy that they waited until their child was asleep before injecting them, hoping they would not wake up. There is a difficult transition period when administration changes from parent injecting child to the child self administering and taking responsibility for their therapy. During this phase, parents were accused of nagging by their teenage children when checking if they had remembered to adhere to their daily administration. Therapy

adherence and monitoring were concerns for parents and requirements for clinicians.

The sensitive issues of needle phobia and pain were also expressed by children and adults alike. The most concerned adults were grandparents who occasionally looked after their grandchildren for a weekend and were nervous about all aspects of the administration.

As well as the emotional problems, there were concerns about practical issues like the number of steps required to prepare an administration, remembering the correct dose, accidental actuation of injection mechanisms before the devices are in position on the injection site, knowing how long to hold the needle in the body to ensure the complete dose is injected and knowing how to manage split doses (when a complete dose cannot be given from one drug cartridge).

To address all these challenges, the decision was made to develop an electro-mechanical device. The following features were incorporated to address the emotional and practical issues:

- Doctors input a PIN protected, preset dose on the device. A log is automatically kept of the date and dose at each injection allowing parents to check their child's adherence (without nagging) and doctors (via an IR download feature) to monitor the efficacy of the therapy.

- The device automatically uncaps the needle and retracts it into a recess and recaps when finished so the needle is never seen.

- Comfort settings were included to allow patient adjustment of parameters like the depth and speed of injection. Offering choice gave individuals the feeling of control over what is in reality negligible pain.

- A large illuminated actuation button acts as a traffic light system to inform patients of status – when it is ready to inject, and when it has finished.

- Sensors prevent accidental actuation when not on the skin and trigger an alert if an out of date or wrong drug cartridge is inserted.

- A dose management system minimizes waste between cartridge changes.

- The non-medical appearance of the device and the personalization features like holding screen and rear picture frame creates a non-threatening product for children but still gives confidence in the reliability and accuracy of the device to parents and clinicians.

3.0 Summary of Results

3.1 Other Influencing Factors

Pharma companies are legally not allowed to advertise their therapies so the success has come about through recommendation from doctors, nurses and patients who have experienced the value added by the easypod™.