

Lifting the lid on medical design

In PRW's second Medical Devices Forum, designers and materials companies were brought together to discuss trends and issues in this vibrant sector. Written by Ian Valley

Medical treatment has come a long way since the National Health Service was established almost exactly 60 years ago. As drugs have increased in sophistication, so too have the devices that deliver and support them and this has added to the pressure on the designers of these devices.

But technological progress is not the only challenge that designers face; they must also wrestle with ever more demanding customer expectations. This was one of the conclusions reached by a group of leading designers and materials suppliers brought together by PRW to discuss trends in medical devices.

Of course, customer expectations vary tremendously depending on the sector. The medical devices industry is huge - worth an estimated €180m worldwide - and



Jo Hippolyte of London Associates

encompasses everything from disposable surgical instruments to homecare diagnostic kits. However, as Alun Wilcox, director of medical at PDD, pointed out, both ends of the medical devices spectrum have one thing in common - they require that the designers get the functional aspects right and combine these into a well-considered design.

He added: "We employ behavioural psychologists and anthropologists and all sorts of other 'ologists' that understand what it is like for particular patient groups to live with a condition. An injector

device has a completely different functional requirement - not only in terms of the drug delivery, but also in terms of the usability - for one particular patient group over another. So we conduct research in order to understand what those drivers are before we design the product. Our job is to understand the needs of individual patient groups and translate them into functional products."

Demanding patients

Stephen Knowles, managing director of Industrial Design Consultancy, agreed and suggested that one of the main functional aspects of many medical devices was discretion: "People don't necessarily like to show off that they have an ailment and they are taking some kind of drug, so psychological issues actually become very important. It is not necessarily about the effectiveness of the delivery of the drug, it is about the approach that people will take to using that product."

For Jo Hippolyte of

London Associates, patients are becoming more sophisticated in their choice of treatment: "You can no longer assume that people will necessarily go to the GP and be told what they are going to take just because they used to. There is a younger generation out there who, if they have a condition, don't necessarily want to publicise it, but want some control. Some of the drivers that affect consumer markets are translated into medical demands at the lifestyle end because we are seeing convergence in the market as people's lifestyles change. Young people who are cash rich but time poor have higher expectations; they want some control over how to manage their conditions and they want to be able to integrate it into their lifestyles."

At the other end of the age range, there is a larger elderly population than ever before and this has big implications in terms of home diagnostics, according to Knowles: "Older people don't want to sit in a hospital to treat



Forum participants:

- | | |
|---|---|
| Andy Dean
PERA | Ernst Poppe
DuPont |
| Stephen Frazer
Frazer Designers | Alun Wilcox
PDD |
| Jo Hippolyte
London Associates | David Eldridge (chair)
Plastics & Rubber Weekly |
| Alistair Kingsland
Minima Design | Sponsors' representatives: |
| Stephen Knowles
Industrial Design Consultancy | John Brenchley
Distrupol |
| Paul Morris
Addmaster | Andrew Featherstone
LyondellBasell |
| | Pierre-Alain Weiss
LyondellBasell |

their conditions; they want more products to support them in their homes... The type of devices you need to develop if you have a drug that needs to be taken three times a day is different from that if you are taking it once a month. You get more familiar with using a device on a three-times-a-day regime than once a month so the latter needs to be easier to use. Equally, maybe you can afford to dispose of a device once a month whereas you can't necessarily clear disposable devices away every day. These sorts of factors start to influence the way products are developed. Remote monitoring and the internet are creating a whole range of possibili-

ties and extra treatment options for people who otherwise might have to do without or attend a clinic every day."

NHS strained

The ageing population is also placing considerable strain on the limited resources of the NHS. Hippolyte put it this way: "If you have a larger older population you need to offer constant support. People being sent home early could be a symptom of a system that is under stress."

There remains too little emphasis on prevention of illness, according to PDD's Wilcox, possibly because "there is not a lot of money in prevention".

He believes that the health system is too



Andy Dean of PERA



Stephen Frazer of Frazer Designers

reactive and that medical/pharmaceutical companies are producing products to satisfy the needs of people when it is almost too late. He added: "I was at a technical innovation conference earlier this week and all of the discussion about home monitoring and what technology can do for us now was from technologists talking about what is technically possible. There was no consideration of usability of that technology by individuals. For example, we have looked into this and discovered that old people don't want to wear a pendant around their neck because it signifies they are old. So it is useless; it doesn't work for them."

Andy Dean, director of materials at research organisation PERA, agreed that too much technology was being pushed at people who did not want it. "You have got to go and talk to the market, find out what people want and then refer back and see what technology is there; you need to answer the question 'is there anything

that will solve the problem or does something need developing?"

Stephen Frazer, managing director and principal consultant at Frazer Designers, said his company always made a distinction between "pseudo" and real medical devices (which, he said, essentially comprised diagnostic and drug delivery devices): "There is a bridge between personal care and medical which is quite an interesting soft border," he said.

Many health problems -

such as smoking, drug abuse, obesity and alcoholism - are arguably more social issues than medical and, for Frazer, this creates a fundamental problem: "A lot of medical devices are subsidised by drug companies. I'd say it is almost a matter of following the money; that's the problem. A lot of these delivery systems are there to deliver a very expensive drug and they don't get involved that much in areas which don't make money. Problems like smoking, being overweight and drinking may be where designers ought to be spending more time and effort."

Young and old

Ernst Poppe, global development manager - healthcare - DuPont Engineering Polymers, identified two opposing trends in medical devices. "One is the miniaturisation, particularly for the mobile population who want to have devices with them. So the devices are smaller, more functional, more reliable, and will have to contain a lot of very precise components with high rigidity and stiffness to work properly."

On the other side, he said, the demographic was changing as people lived longer, and older people liked larger, simpler devices: "The new device is twice as big - the screen is easier to read; instead of three buttons there are only two. [Older people] want an easy to use, reliable device for their homecare."

PERA's Dean believed the trend towards homecare for an ageing population had other implications too: "With



Alun Wilcox of PDD



Ernst Poppe of DuPont Engineering Polymers

places in residential homes declining, there is more and more reliance on families looking after older parents and that kind of thing and I think there is going to be more requirement for remote monitoring and diagnostics so people can have some kind of life while being reassured that the parent is safe and well and is taking their drugs at the right time."

Poppe believes the drive for much medical device development is coming from the pharmaceuticals industry: "Drug development is taking longer, with more regulatory requirements to fulfil. Therefore, the patent protection is no longer sufficient payback." This, he said, meant that pharmaceutical companies were looking for increasingly complex

devices to deliver drugs to extend the product's market life. This would lead to specific devices for particular drugs so that they were less easy to copy.

Pierre-Alain Weiss of LyondellBasell agreed that, logically, the pharmaceutical companies were interested in the longer term patents. "But there is another aspect and that is a cost reduction regarding, not the device, but the drug itself, so it may be easier to reduce National Health costs and on the other hand there is a lower risk, less side effects."

Hippolyte pointed out that there had been deregulation of drugs in the NHS: "Deregulating a drug inevitably means it becomes more widely available and it can be bought over the counter. This impacts on the market because it allows companies to change what they do and how they reposition those drugs - generally to a wider

► Continued on page 8

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► Continued from page 7

audience. If you can buy a drug over the counter, you don't need a prescription so you don't have to go to a GP. Therefore more people are likely to buy it. So I think there is a trend developing whereby the government specifically deregulates mature drugs that have been around and tested and they know what the side effects are and how they can be managed."

Alistair Kingsland, design director of Minima Design, says that, as a product comes closer to the end of its patent, and generics begin to be developed, the originating company has to "get its brand in people's minds so that's the one they ask for; there is a loyalty behind that brand".

However, there are other trends in medical devices that are unrelated to drugs and are more to do with procedures. For Knowles, one of the big drivers relates to the major costs in



Paul Morris of Addmaster

Western healthcare in people's time: "If you can increase treatment efficiency there are roles for devices," he explained, adding: "The other thing is the way the market is funded. In Western healthcare systems you

often find that doctors can buy a piece of equipment for a procedure and that is an ongoing cost, but a piece of capital equipment has to go through a budget that has to be approved. That slows the whole process down so it is often easier to buy a disposable device than a piece of capital equipment that does the same job. This happens with surgical instruments and it can happen with therapeutic devices too."

There are many opportunities to use plastics in therapeutic devices, but their use in surgical instruments is more problematical, according to DuPont's Poppe. He explained: "If you find a country that makes more than, say, 20,000 [surgical instruments] a year you have a good opportunity. But most of them make a certain device that is tailor-made for a certain staff surgeon who likes the shape or the colour or the fact that it is stainless steel and they only make between 1,000 and 5,000. It is very difficult to



Alistair Kingsland of Minima Design

syringes, for example, there is a big move in this direction. Sometimes, it is just easier to throw something away rather than clean it and track it."

Part of the reason for this trend could be a growing awareness of the dangers of infection. Kingsland pointed out that there had been developments in anti-microbial plastics so that the plastics themselves were helping to keep infections at bay. And disposable instruments can make sense to reduce the risk of exposure to Creutzfeldt-Jakob disease (CJD) and other contagions.

Safety first

Paul Morris' company Addmaster produces an anti-microbial plastic additive that uses silver ion technology, but he has found NHS trusts unresponsive. "We would go to a trust when silver ion technology was quite new and say why don't you look at this technol-

ogy? We have had very senior members of a trust say we are too busy fighting MRSA to look at anything new."

Addmaster has had more success with its anti-microbial product in the US, where hospitals fear litigation from patients who contract MRSA.

The overriding consideration when selecting materials for medical devices is safety, according to Pierre-Alain Weiss of LyondellBasell: "Designers who approach us tend to see first what is available. I have probably only had a single request from a designer asking for a new material and the volume was so low that it was not even worth considering. Usually it is looking to see whether there is a material that is already proven with all the regulation approvals. This is why I keep saying to designers 'please involve us before you make a selection first of all to see that the material you are choosing is the right material and also to see - we may have something in our drawer that you don't know about'."

He said there is innovation in plastics materials, but pointed to a "Catch 22" whereby a material did not necessarily become commercial until it was on the market where everybody could see it, but it was difficult to find a market before it was commercialised: "When it is commercial, everyone sees it and they start asking about it. So

Growing market



PDD designed the Merck Serono easypod auto inject device for growth hormone therapy which the company says is the first electronic device in this therapeutic area. It was designed to improve patients' ease of daily use, reliability and convenience. It has been developed in conjunction with parents, their children and healthcare professionals and as a result meets the need for therapy compliance, traceability, safety and dose control as well as addressing the sensitive issues of needle phobia and the perception of pain. PDD says the design was aimed at embodying confidence and control for parents and be non-threatening, approachable and have the ability to be personalised by children.



John Brenchley of Distrupol

you need people asking you before you have it on the market."

Knowles added that a range of materials already existed that could prove incredibly flexible: "People talk about innovation and of course it is vital not to stop progress. But what is important is that you get reliable data. Designers and engineers have been working with a lot of these materials for decades - they know the applications and properties and what they are good for; there is a whole case history of products on the market that show these polymers work and are good in certain situations so it is not as great a leap into the unknown as far as the technology is concerned."

Material world

For Wilcox, the materials suppliers could support designers with better simulation in the form of computational fluid dynamics (CFD) and finite element analysis (FEA). He said: "Sometimes it is difficult to get all the data that you need to produce a really good simulation; a lot of the time it is because the data simply doesn't exist. Suppliers could help us a lot by sourcing that data and supplying it to us."

Kingsland added that the free issue of small amounts of material would also help in order to allow the designers to run their own tests, but Frazer pointed out that it was not just the materials: "It is also the know-how and the service in terms of whether it is small quantities, batches and so on."

Weiss agreed. Indeed, he went further: "The trend that we see is moving towards guarantees in consistency for the material to lower your risk. This is not only about the material specification, but also about long-term delivery guarantees, the supply of material, alternative plant in case of manufacturing problems, and so on."

Frazer sees a potential problem with the latest generation of designers: "One of the difficulties with a lot of the designers coming out of college now is that they don't have



Andrew Featherstone of LyondellBasell

workshops, they don't make models in the way that we used to and they don't have a feel for the materials in the same way. They are working entirely in a virtual CAD world and very often they don't see these sorts of issues as their problem."

Knowles agreed: "But it is not just designers - I think there are a lot of experienced design engineers specifying materials who understand what it is about. But clients' marketing people are not always used to materials selection and, in these circumstances, having something physical to show people is invaluable, whether to choose materials or finishes or textures or colours."

Wilcox said that few designers and engineers were polymer experts: "Certainly they may know a lot about the specification, but they don't necessarily know about the problems of processing so we rely on the expertise of the people that support the industry

and that means the manufacturers and moulding companies as much as the materials suppliers."

Recycling

The debate moved on to plastics recycling and, although there was general agreement that there was no scope for this in contaminated medical devices, Knowles thought it may be possible in the case of packaging and casings for devices.

Weiss said his company often had questions from customers about green materials and about the environmental fingerprint of different polymers. Reusability was rarely an option: "In the beverage industry you will find people asking you about bottle-to-bottle recycling. No-one ever asked me about syringe-to-syringe recycling! It is more about having an understanding about the ecological impact rather than looking for new classes of polymers."

The environmental

impact does affect how medical devices are designed, according to Knowles: "People don't want to be overly consuming or throwing away things that are perceived to have value so there is a design challenge to make devices as minimal as possible and if they can be reused sensibly then maybe they should be reused. But I think, ultimately, there are so many other industries that have a much bigger impact on the recycling issue, and without the conflict of interest."

Besides, said Poppe, people wanted predictable materials and "degradable plastics become unpredictable and cannot be used in advanced medical devices. There may be speciality plastics that can be dissolved in the body, but pure biodegradable resins in medical devices for the time being, no. Our customers want to have plastics that are entirely stable over the next three to five years and they do not want to have any decline in strength."

Pens hit the mark



Industrial Design Consultancy designed and project managed these insulin pens in both disposable and reusable versions for Indian consumers. Indian company, Wockhardt, was keen to introduce affordable pens but the patent restrictions on existing designs were such that they were unable to cost-effectively go into production. In order to overcome this, Wockhardt contracted IDC to design a completely new insulin pen, which would give class-leading functionality and avoid all the existing patents. The pens are manufactured entirely from plastic and the internal mechanisms developed give an audible and sensory click when setting and delivering a dose. They also allow dose resetting without wasting medicine, and the reusable product features a magnifying dose window. IDC's md, Stephen Knowles, said: "Manufacturing such complex devices entirely from plastic is a real feat of design and engineering which we hope will enable many more people to have access to convenient diabetes care."

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