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Patient-centric Pharma: Brave new world or same old empty promises?

Hedley Rees explores whether patient-centricity in pharma has really arrived and whether it really is attainable.

Patient-centricity in Pharma is upon us!.....or is it?

The word on the street is that Pharma companies are finally wising up to the fact that they have to focus on patients and deliver what they need, rather than merely focusing on selling drugs. Dialogue is moving on afoot as some of the early adopter Pharma companies are engaging their patients over what they need – and don't need. Even the ugly words 'side effects' are now openly mouthed as never before. This is all good news for patients, isn't it? Patients will finally start to get more affordable drugs, with less side effects and much improved therapeutic benefit as each new generation of drugs come to market.
Well, actually no, that won't happen; and this is why. Fifty years of discovering new drugs through serendipity doesn't disappear in a flash, there is at least a generation of change required. The old tried and tested strategy of 'find it, file it, flog it' is deeply ingrained in the culture of an industry in denial.

Illustrating the point

Consider the following metaphor. Little Johnny and Jimmy are 10-year-old's attending the same school. Johnny has wealthy parents and has wanted for nothing all his life. Endless sweets, chocolates, sticky buns and fast foods have been in limitless supply from birth (well, not quite birth, but you get the gist). His parent's trips to the supermarket were a joy to behold, as they returned with bags burgeoning with treats and fancies for Johnny. Jimmy on the other hand is from a family that has always found it difficult to make ends meet. Aside from some charitable donations at Christmas time, luxuries have been few and far between. The majority of their food is grown in the garden; supplemented only by the basic necessities purchased at the local shop (they didn't have a car). Jimmy is extremely envious of Johnny, as you can imagine.

Then, one day, Johnny's dad is made redundant from his highly paid job. Not only that but the stock market in which he had invested most of his not insignificant savings then crashed. Suddenly, food on the table was a major issue, as trips to the supermarket were now out of the question. Provisioning from the garden was beginning to seem like an attractive proposition for Johnny and the family.

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Now, what chance do you think they have of making that kind of life style change any time soon? They probably wouldn't know what a seed looked like if it got up and bit them. Nor what type of soil is best for the various vegetables, or how to prepare the soil and a thousand and one other things they would need to know to grow vegetables successfully. By this time, Johnny is extremely envious of Jimmy, who had grown up having to do his fair share in the garden.

Returning back from the metaphor to the real world of pharmaceuticals, with patients replacing vegetables, the industry has now opened the back door and taken a step out into that unfamiliar 'garden' territory – it's actually talking with patients.

Will talking with patients help?

Looking towards the metaphor again for answers, talking with patients is a bit like asking the vegetables what makes them so big and strong. They wouldn't have the faintest idea how they got to where they were. You would need to be a gardener to know that, and Pharma has never been a fan of gardening, in the metaphorical sense. Pharma has grown up taking trips to the supermarket to get its food.

Conversations with patients are necessary of course, in the same way it is important to keep going out into the garden and see how the beans are doing – and that can involve some very deep understanding of the needs that vegetables have; but it is a delusion to believe those interactions will change anything, not unless the family itself changes its ways – and there is no sign that is happening.

Earlier on, I used the words 'find it, file it, flog it' to describe the pervading strategy in the industry. Not wishing to sound flippant here, but this seems like the best way to describe it in stark terms. It goes like this. One group of scientists go off to find molecules that could make it to market (with very limited evidence). They then had it over to another group whose job it is to get regulatory approval, while they go off to find more. Then it gets handed over to a third lot with the task of making and selling the 1 in 250 (US Government Accountability Office official figures) that make it that far, with the major focus on selling it, manufacture occupy a position lowest on the pole.

The conclusion I have drawn as a practitioner in the industry, is that the current drug development paradigm is

no longer fit-for- purpose. It was the best there was 50 years ago, when disease was wiping out entire populations and trials in humans were the only way of proving safety and efficacy to the required standard. This is not the case today, as the technology for ex vivo assessment of drug candidates has moved on almost exponentially….but we still develop drugs the same way.

Pharma companies are unwilling to take the time at the critical early stage – when that bespectacled research scientist

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emerges from behind a wall and lays a test tube of white powder on his bosses table labelled "Handle with care – blockbuster material inside"; and so, his boss gets that handed over the wall to the pre-clinical teams, tasked with growing the blockbuster inside (along with the other 249). The 'birthing' scientists disappear, hoping to be well clear by the time it comes to light that the compound isn't living up to its original promise. The new parents have no alternative but to run with it, warts and all, the patent clock is ticking…..

The rest of it I leave to your imagination. For all kinds of reasons, the molecules fail; and many if not all of the failure modes could have been predicted at the start. Often the one that eventually gets there is only marginally differentiated from competitive offerings – hence the need to sell, sell, sell.

For those readers still with me, there is hope – but only a glimmer. It requires a totally new model for product development, which entails a paradigm shift in the industry psyche – drugs must now be designed, made and sold with the end user (patient and healthcare practitioner) a central focus, in the same way every other sector in competitive markets has to do it. It must start with a deep understanding of the end users specific needs for their particular indication.

What could a new model look like?

The regulators have already pointed the way. Dr Janet Woodcock, Director of FDAs Centre for Drug Evaluation and Research (CDER) challenged the industry nearly 15 years ago (21st Century Modernization), to look towards other sectors and model their behaviour on best practices in those sectors. Not only has this not happened (well, maybe the occasional glance) but there has been no improvement in attrition rates and innovation and much of the evidence (eg from Tuft's) points towards worsening indicators of performance. So what is going wrong?

We get a clue from Taiichi Ohno (at Toyota). He had the foresight to observe a fundamental change in the market for automotives in the 1950s and 1960s. These were the drivers for change:

1. Instalment payment plans
2. Used car trade-ins
3. Sedan-type body
4. Changing models yearly
5. Improved roads

From that, he concluded that customer markets were moving way passed the one size fits all paradigm of the Model 'T' Ford. In effect, he had predicted the end of the 'Blockbuster' auto era. Customer markets were becoming more segmented, increasingly seeking variety and customisation. The days of producing huge volumes to drive down unit cost, often at the expense of quality, were numbered. Customer was becoming King.

Accordingly, a new model for product development emerged. R&D 'throwing it over the wall' for others to make the best of was deemed inadequate in markets seeking variety and customisation. The message was to build a deep understanding of the value proposition that would capture the imagination of end customers – and then seek to deliver that by building a production system to deliver on that value. Is Pharma geared up to deliver that?

This is where the dilemma lay for Pharma. The 'gardening' that Pharma has to do is to engage deeply with patients, not just talking to them, but knowing them better than they know themselves; then developing products that fulfil the needs of patients and their healthcare practitioners.

In the next article, we will explore how Pharma could start an excursion into the world of gardening and so enter the 21st Century – with a 'New model for product development'.

Closing thought: Is talking with patients enough to help pharma?

About the author:

Hedley Rees is author of "Supply Chain Management in the Drug Industry: Delivering Patient Value for Pharmaceuticals and Biologics" (J. Wiley 2011) and is a practising consultant, coach and trainer. He helps healthcare companies build, manage and continuously improve their clinical trial and commercial supply chains and risk profiles.

Hedley Rees is the Managing Consultant at PharmaFlow Limited, a UK based consultancy specializing in supply chain management within the pharmaceutical and life sciences sector. Clients range from large pharmaceutical companies to emerging biotech, and also include investors, lawyers, other consultancies, facility design & build specialists and third party logistics providers (3PLs). Assignments span early stage clinical trial supply chains up to complex multi-product supply networks covering global territories. Prior to this, Hedley held senior positions at Bayer UK, British Biotech, Vernalis, Ortho-Clinical Diagnostics and OSI Pharmaceuticals. His skill set covers the range of competencies from strategic procurement, production and inventory control, distribution logistics, information systems and improvement. His specific interest is in driving industry improvements through the regulatory modernization frameworks of FDAs 21st Century Modernization and ICH Q8 – Q11. His early career was spent as an industrial engineer in the automotive, consumer durables and FMCG sectors.

Hedley holds an Executive MBA from Cranfield University School of Management and is a corporate member of the Chartered Institute of Purchasing and Supply (MCIPS)), an advisory board member of the international institute for advanced purchasing & supply (IIAPS) and a former member of the UK BioIndustry Association's (BIA) Manufacturing Advisory Committee. He is an advisor to a number of UK Government initiatives driving improvements into the Pharma supply chain and is co-chair of the highly regarded FDA/Xavier University sponsored PharmaLink Conference held in Cincinnati annually. He is also widely published in US and EU pharmaceutical journals.

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