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

Hedley Rees concludes his exploration of the concept of 'patient-centric pharma' and questions what the barriers actually are to achieving this.

(Continued from "Patient-centric Pharma: Brave new world or same old empty promises? Part two")

Where does the patient ACTUALLY fit?

In Part two of this three-part article, I maintained that Pharma is still issuing empty promises on patient-centricity; and there are substantial barriers to overcome before it could take hold in any meaningful sense. So what are the barriers to a REAL patient-centric Pharma? To answer the question, we need to return to the basic assumptions outlined in Part two, as they relate to patients. Currently, the industry starts with a patented compound and looks for an indication in which it may show safety and efficacy. At this point, the patient doesn't come into the equation.

The favourite indications are those with unmet medical needs, or 'blockbusters' by another name. The focus is almost entirely on the size of the potential market and the net present value (NPV) calculations that ensue. Those with NPV's that exceed the threshold values, and have some limited evidence they may be safe and have some biological activity, are progressed through to development candidate status. At this point, the patient doesn't come into the equation.

The next stage on the journey is through preclinical assessment in preparation for entry into the clinic. The aim here is on gathering enough data to justify a first-in-humans study and submit an application to run clinical trials. Since it is clinical data that generates most of the excitement around a drug, the race is on to get through the preclinical phase with as little delay as possible. At this point, it is only test tubes and animals that come into it.

Now, at last, the patient comes into it, in terms of recruitment for the studies and what is / are the end-point(s)? The data from the studies are gratefully soaked up into the eventual regulatory submission. At this point, the patient is a source of data, a passive provider of information.

"So what are the barriers to a REAL patient-centric Pharma?"

Finally, for the one in 250 development compounds that eventually make it to market the patient comes into it in a BIG way. This notion is captured nicely in this month's edition of Pharma Times where Kevin Grogan

quotes Jeremy Levin, recently departed CEO of Teva, speaking at the FT Global Pharmaceuticals and Biotech conference, saying "The minute before you launch your drug, you know more about it than anyone else….But one minute after, patients know more about it than you".

If the foregoing has still not convinced you that Pharma is a million miles away from patient-centricity, maybe that quote, from one who should know, will?

Where does MARKETING fit in?

It is not just the patient that is left out of it, Marketing is too – listen to the words of Jo-anna Allen, a highly experience Pharma marketing executive "In my experience, marketing is involved too late in the research and development of drugs. The

search for medicines to meet unmet clinical needs means that the end user is secondary to the clinical data which prove that a drug is working. This is compounded by the fact that sometimes drug discoveries are stumbled across as they are developed with one disease area in mind but are licensed for something totally different (e.g., Viagra, Provigil). This leads to a "take it or leave it" approach, where marketers and sales people are allocated responsibility to market and sell a new product over which they had very little influence. To me, this situation is unique to pharmaceuticals; in other sectors marketing would represent end-user needs and play a key role in research and development."

That view was expressed to me by Jo four years ago and captured in my book[1]. It still holds true today.

"This then is the massive barrier – an ingrained cultural mind-set that drives behaviours counter to the needs of patients."

Has Pharma gone too far?

This then is the massive barrier – an ingrained cultural mind-set that drives behaviours counter to the needs of patients. If a miracle occurred and the industry was to commit to radically changing these cultural assumptions, it would still be faced with an enormous secondary barrier created by this under-pinning mind-set. Thirty plus years of jettisoning the hard grunt of developing and making drugs (in favour of finding and flogging) raises the major question of Pharma companies going too far? Those familiar with the work of Professor Andrew Cox[2], world renowned strategic procurement and outsourcing guru, will recall his warnings about the loss of critical assets, adverse selection and moral hazard (ie once the contract is signed, the power shifts from buyer to seller). These all heavily impact the ability of a company to create and exploit its competitive advantage. Whilst many industries have outsourced certain competency sets to great effect, none if any outsource the ability to design and develop their products – and those that do go to the wall; but that is exactly what Pharma has done. The critical assets needed to develop, manufacture and distribute drugs are in the hands of contract research organisations (CRO's), contract manufacturing organisations (CMO/CDMOs), wholesalers and third party logistics providers. The relationships are almost entirely arm's length and cost based; and the power play has reversed, as sponsor companies become locked-in to those contractors they have so successfully trained and mentored through the process of disconnection from the mothership.

Disease has taken hold of the industry

So now there is a substantial and debilitating dislocation in the industry. As I researched my book in 2009, I gave it a name - 'Serendipity Induced Chronic-disconnectedness accompanied by Change Inertia (SICCI=sicky)'. That may sound like a terrible pun, but in fact there is a serious message behind it. The industry is suffering from a disease that not only prevents it from engaging with patients, it also prevents it from operating sustainable business models based upon competitive differentiation. These models all start with the fundamental principle that long-term success is based on customer satisfaction. Pharma companies have willingly given up control over their ability to innovate, raise productivity levels and drive out cost due to this life threatening condition.

Is there a cure for the disease?

There is a cure, but it will take at least a generation for the medicine to take full effect, and probably longer. That is on the assumption, of course, that the patient takes the medicine in the first place and remains compliant through difficult times; and it is a bitter pill to take, as the initial side effects drive away once loyal 'friends 'seeking the company of healthier folk. Only those truly committed to the cure will remain and share in the eventual joy of a new life.

"…now there is a substantial and debilitating dislocation in the industry…"

What is this magic cure then, I hear you ask? It is real and sustained efforts to modernise by harnessing the platform afforded by the regulators and, in true X-Factor style, making it its own. As mentioned in Part one, both FDA and the International Conference on Harmonisation (ICH) have been pressing for a new, modernised approach to developing and making drugs – termed quality by design (QbD)[3]. The underlying argument for QbD is that the basic principles of developing and making products have been established in other sectors that have been through major change in order to stay afloat. Pharma

senior management has, to date, delegated this to the foot soldiers as it continues to play the old familiar war games of the past. Understandably, these brave soldiers are getting no-where and often being driven backwards and off the battlefield entirely. Modernisation is going nowhere as it sinks under the weight of executive neglect.

What's to be done?

In a nutshell, Pharma must change its basic assumptions that are firmly rooted in the 20th Century. Serendipity is dead, dis-integration is dying and change inertia is no longer an option. Now we get to the difficult bit, what needs to be done to change?

Firstly, Pharma CEOs and their executive teams must step up to the plate and drive a new culture of patient engagement, not only talking to them, but building a deep understanding of their needs, across diagnosis, therapy, after-care and prevention. A crucial element of this will be adopting proper market segmentation approaches as outlined by Professor Malcolm McDonald in Part two, which in turn means getting marketing involved at a much early stage. The industry needs to get much smarter at identifying patient segments and providing solutions to their specific needs.

Once at the plate, CEOs and executive teams need to begin the process of re-connection with their critical assets that presently run the show, build meaningful two-way dialogue with regulators and most importantly of all, must sit down with its investors and explain that quick returns are a thing of the past.

References

1. Rees, Hedley, "Supply Chain Management in the Drug Industry", J Wiley &Sons, 2011

2. Cox, Andrew, "Strategic outsourcing: avoiding the loss of critical assets and the problems of adverse selection and moral hazard, Business Briefing: Global Purchasing and Supply Strategies, 2004 pp. 67-70.

3. Rees, Hedley "Cutting Through the QbD Foliage, Aiming for the Roots" Pharma QbD, Putman Media **http://www.pharmaqbd.com/rees_aiming_for_roots/** Accessed February 20 2014

Closing thought:

What are the barriers to a REAL patient-centric #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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