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Heralds of change

In a recent article for Clinica, the must-read news source for most medtech professionals, I wrote about the megatrends shaping the sector. Although the details of how they impact on the market are specific to each sub-market and product category, these megatrends apply broadly medtech and, to a large degree pharma too. I found it interesting therefore that the papers in this issue of the Journal of Medical Marketing reflected many of these trends and provided a much richer, empirically based description of them than I could in that short article.

The paper by John Bredican, Adam Mills and Kirk Planger is a good example of how mobile technologies, especially smart phones, are shaping the market. As the authors report, this impact is very broad and both direct and indirect. It changes how patients consider their own health and how they interact with healthcare professionals. The problem or challenge for medical marketers is to make sense of these changes and so anticipate the business opportunities and threats they create. The authors of this paper make a useful contribution in this direction, positing a theoretical framework that helps us to see through the hype and understand what is going on in this area. I was especially happy to approve publication of this paper because of its usefulness to almost all medical marketers.

Not unrelated to mobile technology is the huge expansion of chains is not a good use of resources. T...

Our last two papers in this issue both consider emerging markets, which are arguably the most important megatrend shaping the sector. The paper by Mohamed Azmi Hassali, Tan Ching Siang, Fahad Saleem1 and Hisham Aljadhey is based on work in Malaysia and examines pharmaceutical price wars amongst community pharmacists there. It reveals a complex story of interaction between the pharmacists, local legislation and pharmaceutical company marketing practice. This really is the “sharp end” of pharmaceutical marketing in emerging markets, seemingly far removed from the glamorous world of brand management, but an important factor in the success or otherwise of pharmaceutical companies in these newly important markets.

Our final paper also looks at the retailing of pharmaceuticals in emerging markets, this time in China. For pharmaceutical marketers seeking to penetrate this huge market, this is a very useful paper. It reveals the growth trends in the sector and channel. Using regression analysis, it reveals a number of useful trends. In particular, this work suggests that blind expansion of chains is not a good use of resources.
Rather, the findings suggest that improving the quality of outlets and developing complimentary online channels is a more effective strategy component.

As ever, I hope this selection of papers interests our readers and provides both direct value and indirect, broader value for the time spent reading it. I always welcome readers’ comments and suggestions for content in the Journal of Medical Marketing.

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This issue’s review of peer-reviewed research relevant to medical marketers and published in other journals includes papers relevant to both pharmaceutical and medical technology marketers and topics as diverse as innovation, health economics and the financial crisis.

Our first paper looks at the state of the health technology assessment (HTA) programmes in Italy and examines the consequences of a multi-level structure of HTA agencies in highly regionalised healthcare systems, in this case in Italy. The authors combined interviews with 18 key individuals associated with HTA both at the national and regional levels, with a review of the scientific literature about HTA’s activities in decentralised systems. They find that HTA is in the early stage of development in Italy, although with great heterogeneity across regions, and that the National Agency for Health Services has certainly contributed to HTA diffusion through supporting and training activities. However, they also find that multi-level structure of HTA in Italy has in some way hindered HTA as it has not yet provided full coordination and harmonisation of practices and outcomes across the country. This seems to exacerbate inequality of access to services and technologies. The authors make the challenging but well-founded recommendation that there is probably need to rethink the multi-layer organizational framework of HTA in Italy by leveraging on current knowledge and efficient redistribution of activities across regions. This is a useful paper for anyone involved in HTA, especially in decentralised systems.

Our second paper complements the first by considering the cost effectiveness analysis of health technology. The authors begin from the unarguable position that increased health care spending has placed pressure on public and private payers to prioritize spending and that cost-effectiveness (CE) analysis is the main tool used by payers to prioritize coverage of new therapies. They then argue that reimbursement based on CE is subject to a form of the “Lucas critique” (i.e. it is naïve to try to predict the effects of a change in economic policy entirely on the basis of relationships observed in historical data, especially highly aggregated historical data). From the authors’ perspective, the goals of CE policies may not materialize when firms affected by the policies respond optimally to them. For instance, because “costs” in CE analysis reflect prices set optimally by firms rather than production costs, observed CE levels will depend on how firm pricing responds to CE policies. Observed CE is therefore endogenous, in economists’ terms. When CE is endogenously determined, policies aimed at lowering spending and improving overall CE may paradoxically raise spending and lead to the adoption of more resource-costly treatments. They empirically illustrate their argument data on public coverage decisions in the United Kingdom. This fascinating consideration of the law of unintended consequences is essential reading for anyone working in market access.

Our third paper considers another of the hurdles to gaining access to the medical technology market, namely regulation. This paper looks at the evolution of regulatory institutions across the United States, the EU and Japan. They find that the timing of the medical device framework splitting off from the drug regulatory framework and their diversity are striking. Further, regulatory agencies now face a new landscape: the combination of industry-paid user fees and appropriations, a general pro-business climate coupled with dramatic advances in medical technology, shortage in skilled experts trained in the latest state-of-the-art science, and necessary legal and administrative changes. The paper seeks explanations for the complex structure of medical device regulation by focusing on the meaning of the “life cycle” concept, opportunities for patient voices and the scope of and potential for conflicts of interest between industry, physicians, scientific advisors and regulatory authorities. The paper concludes that the initial international differences between medical device frameworks tend to be mitigated by voluntary global harmonization, but that actual, effective integration into the national regulatory framework significantly depends on each nation’s and the EU’s embedded norms, rules and procedures and politics. For anyone for whom regulation is a significant business issue, this paper is both a useful source and food for thought.

Our fourth paper also considers the regulatory environment, but this time in pharmaceuticals rather than medical technology. It paper investigates how regulation impinged on the launch strategies of international pharmaceutical corporations for new molecules across the main OECD markets between 1960 and 2008. Comprehensive IMS data is used to analyze the international diffusion of 845 molecules from 14 different anatomic therapeutic categories using non-parametric survival analysis. The paper focuses on two main regulatory changes that substantially
reshaped the barriers to entry: the U.S. Hatch-Waxman Act in 1984 and the establishment of the European Medicines Agency (EMA) in 1995. The authors find that legal transaction costs have a significant impact on timing of launch. Further, they report that stringent market authorization requirements for new pharmaceutical products in the United States after 1962 resulted in a significant US drug lag in the introduction of pharmaceutical innovation vis-à-vis Europe from 1960 to 1984. However, financial incentives stemming from the 1984 Hatch-Waxman Act proved effective in closing this lag. A more streamlined EMA regulatory approval process has reduced barriers to entry in Europe, thereby enabling quicker diffusion of pharmaceutical products, yet a marked pattern of delay in the adoption of innovation is still evident due to local differences in pricing regulations. Any new molecule launch strategically takes place first in higher-priced European Union (EU) markets as a result of the threat of arbitrage and price dependency across EU Member States. This is an important paper for anyone in the pharmaceutical sector.

Our fifth paper looks at another factor that influences innovation in pharma, namely merger activity. It starts by consider the conflicting trends that confound the pharmaceutical industry; the productivity of pharmaceutical innovation has declined in recent years and, at the same time, the cohort of large companies who are the leading engines of pharmaceutical R&D has become increasingly concentrated. The authors argue that the concurrent presence of these trends is not sufficient to determine causation and that, in response to lagging innovation prospects, some companies have sought refuge in mergers and acquisitions to disguise their dwindling prospects or gain R&D synergies. On the other hand, the increased concentration brought on by recent mergers may have contributed to the declining rate of innovation. They then consider the second of these causal relationships: the likely impact of the recent merger wave among the largest pharmaceutical companies on the rate of innovation. In other words, have recent mergers, which may have been a response to lagging innovation, represented a self-defeating strategy that only made industry outcomes worse? This is a fascinating paper for anyone who studies the sector.

Our final paper to review for this issue looks at microcap pharmaceutical firms. In particular, this article examines predictors of the future market value of microcap pharmaceutical companies. This issue is problematic since the large majority of these firms seldom report positive net income. Instead, their value comes from the potential of a liquidity event such as occurs when a key drug is approved by the FDA. Readers of this journal will be familiar with the typical scenario for such firms: one in which the company is either acquired by a larger pharmaceutical firm or enters into a joint venture with another pharmaceutical firm. In this paper, the authors use binary logistic regression to determine the impact of the firm’s drug treatment pipeline and its investment in research and development on the firm’s market cap. Using annual financial data from 2007 through 2010, this study finds that the status of the firm’s drug treatment pipeline and its research and development expenses are significant predictors of the firm’s future stock value relative to other microcap pharmaceutical firms. Although this result may surprise only cynics, the paper and methodology is a useful read for anyone working with microcaps or indeed the business development functions of larger firms.

References