Paving the way for PM

The individuality of human beings means that a given therapeutic regimen that works well in one person may be without therapeutic benefit or even prove toxic in another. Poor efficacy and toxicity are a huge burden to healthcare systems, with detriment to both patients and society. Patients suffer from untreated illness or complications, while society faces the escalating costs generated through wasted treatments or dealing with the consequences of adverse events. In the United States, adverse events have been estimated to cost as much as US$177bn annually.[1]

Personalised medicine (PM) – a tailored approach to patient treatment using the right drug at the right time – has thus become a goal for many stakeholders. But despite its recognition as a valuable concept, creating such a paradigm shift has met with many challenges. Pharmaceutical companies have been reluctant to embrace a strategy that may appear as a threat to their blockbuster revenues. Regulatory agencies have grappled to keep up to speed with defining the pathways for oversight of the often highly innovative tests involved. Gaining reimbursement from health authorities is yet another complex area, with the level of evidence necessary to prove the value of PM tests debated. Overcoming these hurdles has proven challenging, with an unequal playing field between the US and Europe.[2]

Successful penetration of high value PM tests has primarily been witnessed in the field of oncology. Further developments in cardiology, autoimmune diseases and neurology are ongoing and are likely to change the healthcare landscape in these medical areas in the near future. Ultimately, the impact of PM should be a more efficient, patient-friendly and cost-effective healthcare system. However, this will require more widespread acceptance and adoption of the PM concept and realisation that this will translate into long-term gains. As such, the timelines that will be necessary to see a significantly quantifiable impact on healthcare systems worldwide may be fairly lengthy. Leveraging governments will be crucial in this process and some positive signs have already emerged, such as the UK investment for better access to cancer diagnostics as well as recent initiatives by the European Commission in Brussels.[3] A concerted effort between the various stakeholders will be necessary to make PM the norm.

1 Cowen & Co: Therapeutic categories Outlook, 2008-1012 Estimate, Cowen Group, NY, USA

2 I Miller, J Ashton-Chess, H Spolders, V Fert, J Ferrara, W Kroll, J Askaa, P Larcier, P Terry, A Bruinvels, A Huriez, Market access challenges in the European Union for high value medical diagnostic tests, Personalised Medicine, March 2011, Vol 8, No. 2: 137-148

3 www.biocentury.com/dailynews/politics/2010-12-14/uk-to-fund-additional-cancer-testing

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