Four trends that will transform healthcare in Europe in 2016

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With 2015 giving some hints of what is to come, the Kaiser Associates European Healthcare team are predicting another year of big disruptions, transformations and innovations as the healthcare industry continues to overhaul outmoded business models.

Gene therapy: The next generation of targeted drug delivery

The emergence of precision medicine has at its core the ability to target diseases with specialised therapies specific to certain types of people with specific genetic genotypes. To increase specificity and efficacy, and reduce adverse effects resulting from a medicine going where it is not needed and harming healthy cells, targeted therapies have been a focus of drug development for small molecules, biologics and, more recently, CRISPR/Cas9 genome editing and gene therapy.

The rapid advancement of genome-editing techniques holds much promise for the field of human gene therapy. From bacteria to model organisms and human cells, tools such as CRISPR/Cas9 have been successfully used to manipulate the respective genomes with unparalleled precision. In 2015, a number of companies invested in the technology, starting with pharma giant Novartis, which signed two separate deals with gene-editing start-ups Intellia Therapeutics and Caribou Biosciences. Just a month after the Novartis deals, AstraZeneca sealed four deals with the Innovative Genomics Initiative, the Broad and Whitehead Institutes, the Wellcome Trust Sanger Institute, and Thermo Fisher Scientific.

In the past few years there has been growing commercial interest and activity within the field of gene therapy with large investments and an array of licensing deals and funding rounds reported. Gene therapy aims to treat diseases by replacing a non-functioning gene with a functioning one. Unlike usual drug therapies that must be taken for months or years, gene therapy offers the alluring possibility of a
one-time treatment, so biotech startups are racing to get such therapies on the market.

2015 saw the European Medicines Agency approval of UniQure’s Glybera (alipogene tiparvovec), a gene therapy that mitigates lipoprotein lipase deficiency, a rare disease affecting only 150-200 people in Europe. This was the first gene therapy accepted by regulators; this watershed augurs future approvals for other such therapies in development.

**Prediction:** In Europe in 2016 we expect to see the approval of GlaxoSmithKline’s GSK2696273, a gene therapy for extraordinarily rare cases of immune deficiency triggered by adenosine deaminase deficiency, or ADA-SCID. Whilst the traditional model of serving large populations of patients will remain true, expect to see increased investment and progress in rare genetic diseases.

**Improbable partnerships:**

**Unlikely marriages in healthcare become the norm**

Traditionally, big pharma relied on the Fully Integrated Pharmaceutical Company (FIPCO) model, whereby each company ran its own discovery, development, manufacturing, marketing and sales for the majority of its product pipeline and portfolio. External relationships tended to be opportunistic: for example, strengthening the sales force for a new product launch through marketing agreements, clinical trial support or via discovery pipeline in-licensing. However, this model has declined as the number of partnerships and mergers and acquisitions (M&As) have risen, driven by an increasing need for innovation, low interest rates, and cost pressures that are hitting big pharma’s research and development spending.

In 2016, M&A activity will intensify in the pharma industry. Companies are looking not only for favourable tax environments, as Pfizer did with Ireland-domiciled Allergan, but for meaningful partners to provide strategic acquisitions through portfolio/pipeline synergy, geographic reach and/or market consolidation, as with generics giant Teva’s acquisition of Allergan’s generics division. Trading business units is also not off the table, as per last year’s GSK/Novartis oncology/vaccines swap.

However, pharma companies are now looking beyond pharma for partners, and the impact of this extended reach will be seen in 2016. If pharma does not team up with tech giants like Google and Apple, they are at risk of falling behind. As a result, healthcare companies have started to search for large-cap technology partners for tech-pharma developments. For example, in September 2015 Proteus Digital Health and its partner, Otsuka Pharmaceuticals, applied for US Food and Drug Administration approval of a sensor-embedded version of its antidepressant Ablify. This builds on years of using a digital health feedback system in clinical trials, but if approved, this will be the first digital medicine-combined-drug-and-device product.

In addition to forging cooperative agreements, pharma companies have also engaged in significant cross-industry collaborations. For example, it was recently announced that GSK and the US wireless telecommunications company, Qualcomm, are currently negotiating the terms of a potential joint venture. Although full details have not been released, one could speculate that this has something to do with Qualcomm Life’s 2net Platform that collects and aggregates medical device data during clinical trials to enable quick, convenient study participant data capture and improve trial efficiency. If this is the case, we could expect that this technology will also move out of the trial setting and start to fuel outcomes-based approaches.

**Prediction:** As the pace of tech developments ramps up, pharma’s tech focus will, too. Expect more technology-oriented team-ups in 2016 as drug makers introduce new monitoring technology into clinical trials – and later, into the real world.

**Pressure on pricing:** Fighting back against rising, non-transparent pharma prices

Pressure from payers is always a concern, but high-profile events such...
as the Turing and Valeant Pharmaceuticals scandals have drawn unprecedented attention to pharmaceutical prices. In the US, public outrage has elevated the discussion into presidential debates as pharma stock prices have plummeted. However, in Europe, pricing scandals are not new developments. Major players such as the UK’s National Institute for Health and Care Excellence have been pushing back on pricing for years, gaining public attention with restrictions on cancer drug pricing (most notably for Roche’s Kadcyla, whose £90,000 (€100,000) price tag was rejected by the National Institute for Health and Care Excellence in December 2015 after prolonged discussions and proffered price discounts). Lack of access to life-prolonging cancer therapies continues to draw attention and puts pressure on pharma companies to negotiate with payers.

In September 2015, France became the 22nd EU country to sign the Joint Procurement Agreement, which facilitates joint purchase of drugs and medical equipment in cases of cross-border threats to health. However, this agreement may also be seen as a challenge on external reference pricing. The reference price used is variable (may be list price, wholesale price, or other price), and transparency on prices used as references is low. Illustrating this problem, a recent study of cancer drug prices across 16 European countries, Australia and New Zealand found that the actual prices paid by countries varied by up to 58% after manufacturer discounts. Prices for the UK, Greece, Spain and Portugal were among the lowest, while prices in Switzerland, Sweden and Germany were significantly higher – by 100 – 200% for 10% of the cancer drugs included in the study.

Prediction: Cuts in healthcare spending in Europe and the rising prices of advanced biologics and pharmaceuticals will drive the market access environment in this space towards an aligned, transparent model whereby costs will be set by open negotiation or joint procurement. While this will be a long-term process, changes will start to become evident in 2016.

Health technology: Driving a tectonic shift in the physician-consumer ecosystem

Technology is permeating the pharmaceutical industry at every turn: clinical trial management, clinical decision support, electronic prescribing and patient management, to name but a few areas.

Physicians can now engage with patients through mobile applications, health devices, social media and online communities, while consumers increasingly use the internet, connected devices and innovative health information technologies to monitor and manage their own health. From the launch of Apple’s ResearchKit in March 2015 to Medtronic’s recent approval for the first remote monitoring app for implantable pacemakers, mobile health is showing evidence of its ability to optimise clinical trials and improve engagement with participants and patients. According to Biogen’s CEO George Scangos, wearable devices will “transform the way we do clinical trials”.

All the big pharma players are getting involved. Novo Nordisk recently paired with IBM Watson Health to develop a big data approach to diabetes care, where real-time data from a patient’s insulin pen or glucose monitor could be matched with the patient’s medical records and lifestyle factors to optimise insulin dose and even provide medical advice directly to patients. In August 2015 Sanofi entered into a similar partnership with Google to develop smart insulin pens and a cloud-based data platform for physicians and patients, while Roche committed to developing smartphone apps to monitor the progress of patients during a Phase I clinical trial of its Parkinson’s candidate.

Given that the market for wearable technologies in healthcare is forecasted to exceed US $41 billion in 2020, pharmaceutical companies will need to decide how to position themselves to compete or collaborate with players in this space, or at the very least build complementary capabilities.

Prediction: The rapid emergence of connected or digital healthcare has the potential to disrupt a pharmaceutical market that has been averse to change. In 2016, the new EU Mobile Health Data Quality Working Group will likely publish guidelines to regulate this growing sector, while digital apps will continue to permeate our lives and wearable tech adoption will accelerate.

References