

# Growth trends in the diagnostics market

"The diagnostics and pharmaceutical industries are doing more and more together, and there are solid reasons for this." So said ABPI (Association of British Pharmaceutical Industries) director general Richard Barker, opening the recent Diagnostics 2008 conference, in London.

"New questions are being asked, such as can diagnostics target pharmaceuticals? Indeed the opportunities have been established, and both sectors could grow dramatically in seeking to target therapy more accurately using stratified medicine," said Dr Barker, who was formerly CEO of Chiron Diagnostics.

Three immediate issues to tackle are: How quickly can we move from mere promise to real, solid commercial tests – ie when can they be used? Can we develop a business model that allows both sectors to flourish? (There has not been one as yet, as both sectors have left it to the other – "and diagnostics does not have the money"); and Can the UK lead in this area?

On this last point, the conference chair observed that there is a lot of promise, and many early-stage R&D projects based around "great ideas" are underway. The UK government is even putting increasing amounts of cash into life sciences, he said, but added that the funding needs to be better targeted: "The government sometimes needs a bit of help." But there is no doubting that the UK has the potential to lead.

Some of these "great ideas" are first heard about at meetings, said Larry McGrath, long-time editor of US-based *IVD News*. "Posters are the best source of trends upcoming," he said, in a presentation designed to give a global overview of the direction being taken by the IVDs business.

"Diagnostics are following the pharma model more now, with abstracts and posters coming out at the preclinical stage, so that they can educate over a 4-5 year period." This is a new trend in an industry that has traditionally guarded its discoveries and work-in-progress jealously.

The world market for diagnostics at present is valued at \$34-36bn, and is disputed in the main by some 300 or so large companies. The top six of these hold a 90% share of the total. But there are a lot of small companies fighting their way in, said Dr McGrath.

## Diabetes drives diagnostics growth

The non-clinical diagnostics sector includes: blood screening (cells and fresh-frozen plasma) – \$2.1-2.3bn; diabetes – \$7.8bn (some five years ago, this was blood glucose monitors, but now it is "disease management", ie it includes pumps). Diabetes is the driver of the diagnostics industry's growth, and indeed the real growth is spurred by the need to monitor for type II diabetes; OEM and distribution sales (which are double-counted) and valued at some \$1-1.8bn; and surveillance diagnostics – \$1-1.5bn, including industrial microbial testing, valued at \$125m (mainly disputed by bioMérieux and BD).

The core clinical diagnostics market is valued at \$22-24bn.

In this, the central lab accounts for 48-52%, but it is an industry showing little growth.

The growth can be found in the microbiology/urology sector, accounting for 8-10%; pathology (flow cytometry and tissue oncology) making up 8-10%; and decentralised testing – ie point-of-care (POC) and physician office tests, accounting for 16-20%. An interesting question regarding the latter is how to define it, said Dr McGrath. On the one hand, use of these products detracts from hospitals' and labs' efforts to achieve growth of test volumes, but on the other, POC is used more in A&E than ever before.

POC fits into the "cheaper, better, faster" model of competing for market share, but where is the clinical need to have the answer *at that moment all of the time?* he wondered. The need for speed must be seen in context, and always against the measure "does it help in terms of clinical, definable actions?", he asserted.

## Basic trends

The basic trend being observed at present is towards automation and instrument segmentation – "one size does not fit all". Today, 30% of labs will buy their chemistry system with an immunoassay system in a workcell or workstation. "This is changing the model," he said. There is also increasing menu parity on the systems, he added.

To compete, companies will need multiple sizes of instruments.

In molecular testing, the winners will be the companies that require only one sample, and use automation for what is a "tedious process". In addition, we will increasingly see new markers – there have been six new viruses identified since 2001, "so new markers will always be in R&D", he said.

Work process automation initially gave rise to fears over loss of staff, but now the worry is over the lack of trained staff.

## "Open innovation" in personalised medicine

Echoing sentiments that a tailored and flexible approach to the market for success was Philips business development director Glyn Colebrooke. The €6.7bn (\$8.9bn) medical systems group runs an incubator in Eindhoven, the Netherlands, where Mr Colebrooke pursues an "open innovation" policy. This, he said, is "the only way that personalised healthcare will be delivered".

And the arguments for the stratified approach are compelling: in 2001, 25% of cancer drugs were effective; in 2008, the rate had risen to 70%, with the use of companion diagnostics, which shows that, for the drug to work, the target has to be known.

On the issue of affordability, he pointed out that in the US, "with spiralling healthcare costs, CMS will be bankrupted" if it cannot get costs under control.

Philips' future plans include bringing digital pathology to the market, in the shape of a blood or saliva-based handheld roadside drugs-of-abuse test that takes five minutes. Concateno subsidiary Cozart will launch the product next year. "What we did for radiology in the 1980s, we are now looking to do for pathology," he said.

## M&A/IPOs and patents

There has been continual growth in M&A in the diagnostics sector, and an ongoing low level of IPOs, in recent years. There were 41 diagnostic company acquisitions in 2006, of which 13 involved POC or decentralised testing, and 13 were in the molecular diagnostic field, said Dr McGrath.

In 2007, the totals were 47 overall, including 18 POC and 10 molecular. The first quarter of 2008 (eight deals) has shown one POC deal and two molecular, and the latter is showing an underlying increase in deal numbers, quarter on quarter. "There is a huge amount of investment in molecular [diagnostics] compared to immuno- and chemistry."

As to patent filings, Roche has consistently been number one over the years, followed by Bayer, Beckman Coulter, Siemens, Abbott, Sysmex, Dade, Applera, Gen-Probe and Lifescan.

By 2010/11 the leaders will line up in the following order, Mr McGrath suggests: Roche, Siemens, Abbott, Beckman Coulter, Johnson & Johnson, Inverness and bioMérieux.

This reflects "a lot of dynamic activity going on in the industry".

• *Diagnostics 2008 was organised by DiagnOx, BIVDA, BERR (Department of Business, Enterprise and Regulatory Reform) and IAS (Innovation Advisory Service – South East), and was held on June 26.*

Report by Ashley Yeo