

WORDS BY BARRY McCALL

PROFOUND CHANGES to how medicine is practised and how treatments are delivered will have a major impact on the global pharmaceutical industry over the next decade, according to a new report published by PricewaterhouseCoopers (PwC). *Pharma 2020: Supplying the future – Which path will you take?* looks at how the global industry will have to radically overhaul its supply chains to meet the demands of a fast-evolving marketplace and the shift in focus from products to patient outcomes on the part of health services and other healthcare purchasers.

The report finds that the pharmaceutical industry is still geared up for the blockbuster era when major new drugs would be launched on to the global marketplace generating billions of euro in revenues annually until their patents eventually ran out. This era has gone, with fewer and fewer global drugs now in the pipeline and the patents on products with sales of more than \$267 billion expiring over the next six years alone.

Something's got to change and it's going to be the supply chain. This is already happening as a result of a number of forces, including an increasing diversity of new product types, the advent of live licensing, an increasing emphasis on patient outcomes, new modes of healthcare delivery, the growing importance of emerging markets, greater public scrutiny and environmental pressure.

Live licensing is among the most important of these. The "big bang" product launch is rapidly becoming a thing of the past. These launches typically involved multi-million euro licence-application processes followed by even more expensive marketing campaigns for the latest blockbuster. This more or less confined the mass market to the major pharmaceutical companies who had pockets deep enough to meet the vast costs.

However, with the very nature of drug development changing, there is a move to more incremental licensing processes as new methods for assessing, approving and monitoring medicines emerge. At present, the marketing applications for most new medicines are either approved or rejected; the supply chains for manufacturing and distributing them are designed to support peak sales volumes; and the revenues they generate climb in a relatively predictable fashion.

But the system of authorising new medicines is becoming more graduated. The European Medicines Agency (EMA) and US Food and Drug Administration (FDA) introduced conditional approvals for certain products some years ago. Both agencies are also placing much more emphasis on post-marketing surveillance, and PwC believes that the current system will eventually be replaced by a system in which new therapies are granted "live licences" contingent on further testing to confirm their safety and efficacy in different patient populations.

This will mark the end of major launches with medicines and treatments being introduced to the market far earlier with testing and monitoring continuing after that point. Furthermore, the medicines are going to be designed to meet the needs of specific patient populations meaning the near demise of mass market products.

"We call these new drugs 'nichebusters' rather than blockbusters," says Ivan Coulter, chief executive of Irish biopharmaceutical development company Sigmoid Pharma. "I would agree that there is certainly a big shift happening in the pharmaceutical industry but, like a lot of shifts, it is not going to be a big bang but a gradual transition. One of the things that's driving this is our greater understanding of the molecular basis of diseases. This is allowing us see why patients will suffer the same symptoms due to different causes and will therefore respond to different treatments. For example, in the past if you had a group of patients with hypertension you would

have given them
all broadly
simi-



lar treatment. Now that we understand the different causes this is driving a stratification of the patient groups to the point where they are receiving different treatments or even different doses of the same treatment."

This ability to treat small groups of patients with similar conditions means that the pharmaceutical companies will have to find ways of getting to those patients. "The pharmaceutical companies need to extend their reach to get much closer to their patients," says PwC global pharmaceutical leader Jonathan Marsh. "This is quite challenging. The regulatory regime doesn't allow the companies to get that close to patients. This wasn't a problem

under the old blockbuster model where the companies developed a drug, put it in a bottle and marketed it globally. In the new paradigm the industry will have to look at different products for different patients with the same conditions. In fact, in the past five years we have already seen the development of formulations which are specific to the individual. The supply chain is in the middle of the relationship between the company and the patient and it has a key role to play in bringing them closer together," he adds.

"There will be a need for more flexible, powerful and modular drug delivery systems and this is where companies like Sigmoid will come in," Coulter points out. "We are already part of the supply chain and we want to become an even more important part of it in the future."

These developments are in turn leading to an increased emphasis on patient outcomes and this will be an even more potent driver of change in future.

"You're going to have a situation where health services and insurance companies will only pay for drugs where they actually work," says Marsh. "They won't pay for lots of patients to have expensive treatments if they only work for some of them. The industry is not only going to have to develop drugs suitable for individuals but will also have to understand the needs of those individuals and learn more about them. The technology and the capability already exists in other industries such as the motor sector and consumer electronics to do this. It is a question of getting the data and using it correctly."

Data will play an increasingly important role. "In a world where outcomes will count for everything, the ability to integrate data, products and services in a coherent business offering that delivers increased value and better understands the needs of the patient is vital," says Marsh. "Companies must now work hard to get closer to their patients, as by 2020, there is little doubt that the data behind a product will be as valuable as the product itself."

PwC Irish pharmaceutical leader John Kelly believes these changes present significant opportunities here. "This has huge implications from an Irish point of view," he claims. "We need to design hubs in Ireland for the full range of services required by the pharmaceutical industry. We need to be not only manufacturing but also engaged in the delivery of products and services. We need to put ourselves in a position to capture the bulk of these services; to become the spider at the centre of the services web so to speak."

He argues that in the future the industry will be about service rather than pills. "Pharmaceutical companies in Ireland need to get involved in the global strategies of their parent companies in order to remain relevant to the organisations. All of the sexy stuff will be in the marketplace and Ireland needs to get plugged into that. The future is all about services, not pills. The world is changing, there are opportunities and threats out there and we need to take advantage of the opportunities." ■

Rise of the nichebuster

With fewer and fewer blockbuster drugs now in the pipeline and expiration dates looming on the patents on many billion-sellers, big pharma is moving away from the mass-market model