The life sciences, drugs and healthcare industry in 2016 and beyond: trends and predictions

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Since the publication of the 2009 Practical Law article entitled "The life sciences industry: trends and predictions", the life sciences industry has experienced a great deal of changes. Lawyers working within the industry have remained incredibly busy thanks to, among other things, increased regulatory pressures, both in terms of costs and marketing, technological innovations and diversification within the broader healthcare and life sciences market. This article considers some of the broad trends lawyers are currently seeing in their practices and discusses their predictions for the future of the industry.

The lawyers interviewed are contributors to the Distribution and Marketing of Drugs Global Guide; the Commercialisation of Healthcare Global Guide and the Life Sciences Global Guide.

Aditi Mene, Practical Law Global

Increased regulation

Lawyers report that there has been a marked overall increase in the amount of regulation in a number of areas, particularly in relation to:

- The marketing and promotion of drugs and devices.
- The cost of pharmaceuticals, devices and other healthcare services.
- New technologies, innovations and integrated healthcare services.

Increased regulation on marketing

Governments in Europe have led the way in terms of tighter regulation in the promotion and marketing of drugs and devices, particularly in France.

In France, Olivier Lantres from Fieldfisher (contributor to the Distribution and Marketing of Drugs Global Guide) notes that a large part of his work involves dealing with the relationship between life sciences companies and the health authorities and navigating the increasingly strict regulatory landscape. He thinks that health authorities have become "less confident" in healthcare companies following the scandals that occurred with the Mediator diabetes drug and PIP breast implant devices, and therefore have become much stricter. Lantres points out that the French authorities are particularly conservative when it comes to what device companies can state on their websites, and are prohibited from mentioning any doctors or practices which might specialise in the specific treatment that the device is for. Lantres states that this is considered to be indirect advertising and therefore prohibited. He considers that, as a result of the various regulatory pressures, France is no longer the first country where life sciences companies choose to launch their new products.

In Portugal, Fernanda Matoso from Morais Leitão, Galvão Teles, Soares da Silva & Associados, Sociedade de Advogados (author of the Portugal Distribution and Marketing of Drugs Q&A), mentions that there is also a strict regulation of the marketing of drugs and devices to the public. Therefore, some companies seem to be moving into client care policies, providing a wider array of services to patients and physicians, such as the training and administering of complex drugs. Matoso states that these policies may raise legal issues due to the current legal framework which, in a strict interpretation, seems not to allow pharmaceutical companies to directly provide these wider services. However, she expects companies are still likely to want to expand their role in complementing their activity as marketers of medicines by providing services related to the administration and adequate and safe use of medicines. As a result, she thinks more companies are going to need the legal help to navigate this and branch out into these complementary services.

In Washington DC, Jeff Gibbs (General Editor of the Commercialisation of Healthcare Global Guide), whose practice at Hyman Phelps & McNamara focuses on devices and Food and Drug Administration (FDA) issues, reports that the FDA and its attempt to regulate promotional material for devices has raised constitutional issues. He notes that a number of recent court decisions concerning the FDA's attempt to restrict "off-label" information have led to companies successfully using the First Amendment's right to free speech as a defence against the FDA. As a result, Gibbs thinks that the FDA's authority to restrict "off-label" information has been "seriously challenged", and will likely lead to the FDA losing more of these cases. However, he raises the point that this is still an uncertain area for device and pharmaceuticals companies, "who are looking at the issue carefully and tending to raise the First Amendment defensively rather than offensively". Gibbs does think, however, that over time companies will start to rely on the First Amendment more robustly and incorporate its principles into their promotional activities.

By contrast in Canada, Jeffrey Graham from Borden Ladner Gervais (General Editor of the Commercialisation of Healthcare Global Guide) notes that historically, Canada has relied upon a largely principle-based approach to the regulation of the marketing practices of pharmaceutical and biotech companies, supplemented by voluntary industry association codes of conduct. However, that is not to say that there is no tension between consumer advocacy groups and the healthcare industry about how the rules are applied; Graham notes that there have been occasions where the pharma/biotech industry have been accused of interpreting their own codes in an unreasonably liberal way. While Graham does not think there is currently much pressure to further regulate the marketing practice of pharma/biotech companies with respect to drugs in Canada, he does think that "it is a matter of continuing concern to consumer advocates, and that governments are likely to carefully watch to make sure that the voluntary codes are adequately protecting the public interest".

Cost pressures

European markets have experienced an almost uniformly downward pressure from governments and state authorities on the costs of drugs. In Portugal, for example, the state, which provides a free national healthcare service, has continually made efforts to control and cut the costs of pharmaceuticals which it buys. Fernanda Matoso thinks that this cost pressure was a result of the economic crisis that many European countries, including Portugal, experienced. She thinks that the huge debt owed by the Portuguese state national health service to pharmaceutical companies has forced some of these companies to try to reshape some of their businesses. Matoso notes that some pharmaceutical companies have transferred their decision-making centres to Spain "because of the Iberian connection", the larger market there, and because this has led to smaller unit costs in Portugal. Matoso worries that the overall result is going to be that pharmaceuticals companies that rely on intra-group sales, and distribute products may find that "in their overall business, Portugal will not be seen as an attractive market".

Similarly, in France, Olivier Lantres reiterates that the pressures on companies to keep reducing the cost of their drugs in France is one of the contributory factors to many choosing not to launch their new products in France. In Switzerland, Oliver Künzler from Wenger Plattner (contributor to the Life Sciences Global Guide), reports that pricing is also a difficult issue for life sciences companies operating in Switzerland, particularly those that produce and sell generic drugs; the price adjustments they are having to make tends to mean their margins are becoming smaller. However, he does note that there was a case in late 2015 where the Swiss Federal Supreme Court seemed to limit the health authority's power, which he thought might lead to a possible relaxation in terms of cost. However, he also noted that with an ageing population across Europe, and their inevitable increased need for drugs, the pressure to keep prices down will continue.

In Canada, Jeffrey Graham notes that the governments are continually seeking ways to purchase on a more cost-effective basis new drugs and medical devices, either individually or on a joint basis. Graham points out that there is also not only tension between governments and pharmaceutical/biotech companies regarding the cost of drugs and devices, but also "tremendous tension between those who are pressing for more access to medicines and governments, who want clear cost-benefit analyses of the new drugs or devices".

New technologies and how to regulate them

Many lawyers in the life sciences sector report that some pharmaceutical and healthcare companies have begun to branch out into new areas of business, in order to move away from some of the regulatory and cost constraints that are placed on their usual types of medicinal products. This means that many companies are starting to develop new and innovative technologies and healthcare solutions.

In the US, Jeff Gibbs notes that one area of interest is surrounding laboratory developed tests (known as LDTs), and whether the FDA will start to regulate these. He thinks if the FDA does start regulating LDTs, it will be a "fundamental change to the entire diagnostic industry". However, despite the fact that the FDA has said that it wants to regulate LDTs, Gibbs thinks that it will likely come up against various challenges from the Obama administration, Congress or the courts, and will also be subject to the outcome of the forthcoming Presidential election. The situation appears to be unclear for the industry.

Another question Gibbs raises concerns the modification of devices which have already been approved, and whether the FDA will attempt to start regulating these. He states that the FDA has existing, but out-dated, guidance on the modification of devices, and so this is an ongoing and, as yet, unresolved issue. He notes that it is likely to "be a while before final guidance comes out", and so this will remain an area of confusion for some time.

In any case, Gibbs notes that the FDA will need to start coming up with new policies as technologies advance and the market begins to change. As an example, he mentions that next generation sequencing will be an important development in diagnostics and the FDA will need to come up with a policy on how to regulate this. He emphasises that the FDA will need to act quickly, because "products are on the market, such as companion diagnostics". He expresses concerns over how quickly and how well the FDA will be able to adapt and keep up with these fast-paced changes in technology and the market.

In France too, Olivier Lantres points out that companies are attempting to find new products and new ways to operate by using mobile phones and "remote medicine". He notes that there are fewer general practitioners in the more rural areas of France, and as a result there is a need to think about new ways of dealing with patients in these areas. However, he also points out that, inevitably, there is a question mark over the way in which the mixture of medicine and new technologies can be reimbursed and that the health authorities will need to find solutions for that.

Interestingly in Canada, Jeffrey Graham has a different perspective on the new technologies developing in the healthcare sector.

While he also reports a tremendous growth in healthcare-related technologies, Graham wonders whether the legal systems need to adapt, particularly in dealing with such areas as genetic testing and reproductive health. These are both areas of public policy discussion in Canada that lack, in Graham's view, fully developed legal regimes. However, Graham notes that these legal gaps have not slowed the pace of innovation and there are exciting developments in a number of research centres in Canada that bode well for the future of the sector in continuing to improve the health of mankind. Graham also pointed out that there was an increased focus from governments in Canada to develop and implement policies to accelerate the commercialisation of innovative applications of biotechnology research that apply not only to human health but also to biomaterials, ag-biotech and environmental applications.

Privatisation of the healthcare sector

Fernanda Matoso reports that in Portugal, in the last few years, there has been an increasing number of private health units owned by private groups. She believes that this "is a trend which is increasing", and even the Portuguese state is improving PPPs in the health sector, where tenders have been launched and public hospitals are increasingly committing to private groups managing in-house private health units. Matoso thinks that the economic crisis in Portugal, with its severe cost-cutting in the public health service, has prompted this need to increase the private sector.

In France, Olivier Lantres notes the so-called "Macron Law", a wide-ranging new law aimed at reforming parts of the economy, could open up the possibility of hospitals setting up privately-owned companies dedicated to providing life sciences services to foreign countries. Lantres thinks that this could be a very important change to the healthcare sector, and could give the idea that France is an exporter "not only of luxury products, but also of life sciences and healthcare". He is optimistic that the law could potentially open up the French life sciences sector to wider markets such as Brazil, Saudi Arabia and Russia, among others. Ultimately, though, he is not sure how the law will change the life sciences and healthcare sectors in France, but he thinks the opening up of private companies within the sphere could be "an example of how things are moving in France at the moment".

Unpredictability of the future

One of the many things that lawyers in the life sciences, healthcare and drugs fields tend to agree on is that the future will be hard to predict.

In Washington DC, Jeff Gibbs reports that there is a lot of uncertainty around the FDA and the policy changes that it needs to make in order to regulate and keep up with the changing market, as well as the increasing use of the First Amendment in the marketing of devices and drugs. In addition, the FDA will also be subject to a number of changes and challenges depending on the outcome of the Presidential election. Finally, Gibbs notes that there have been reports that the FDA is also potentially going to undergo a major overhaul in the way it enforces the law, which currently involves inspections at a district-level. Gibbs points out that "if that happens, it will be a fundamental change". In fact, he thinks there are likely to be many more changes that will take place to the FDA and the market. He acknowledges that this will be daunting for clients, but will be "a great deal of fun for FDA lawyers; two years from now we will be working on issues that we didn't even envision today".

In Europe, things are looking similarly opaque. In Portugal, Fernanda Matoso reports that there is no certainty about the future, other than the continued regulatory and costs pressure on the life sciences market from public health authorities. However, the need for pharmaceuticals to be "creative" in pursuing their business in Portugal and in balancing intra-group goals with the local policies on prices, will be important. Her main concern is that the increasing cost pressures on pharmaceutical companies will risk Portugal not being seen as an attractive market for these companies to work in.

Olivier Lantres in France mentions the new so-called Touraine Law, which will enable class actions in the healthcare sector for the first time. He notes that "this is going to change many things in France, potentially increasing the pressures on medical companies". In addition to his concerns about the increasing regulatory and cost pressures on pharmaceutical and life sciences companies in France, which are consciously choosing to launch new products outside France, he cannot predict where this will take the industry. However, a cautious note of optimism remains when he points out a growing and ageing population will ensure that life sciences companies will always have a market and, arguably, an increasingly important role in France in the next few years.

In Switzerland, Oliver Künzler agrees that cost pressures are going to create changes in the industry. However, he thinks the "outlook for the industry is nevertheless good", with plenty of work for lawyers thanks to hospitals and pharmaceutical companies merging and specialising more in certain markets. He thinks that big pharmaceutical players are likely to continue to merge and have bigger-scale

offerings, because their larger scale will make it easier for them to navigate the market. As an example, he points out that although the Pfizer and Allergan deal did not go ahead, it showed that there was an appetite in the sector to increase market share through mergers and consolidation.

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