Regulatory Writing

TTIP: Good or bad for the pharmaceutical sector?

Section Editor:

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The Transatlantic Trade and Investment Partnership (TTIP) has attracted increasing controversy, particularly in Europe. The TTIP is a trade agreement under negotiation between the United States and the European Union, and affects three main areas: market access, specific regulation, and broader rules and principles and modes of co-operation. The aims therefore go well beyond simply eliminating trade tariffs (which are already fairly low), with harmonisation of regulations and business approaches also in the scope of the agreement.

According to one report, an 'ambitious and comprehensive' transatlantic trade and investment agreement could bring economic gains of €119 billion euros a year[1]. The authors claim that this translates into up to €545 per year in the pocket of an average family of four in the unlikely assumption that the gain is distributed equally. Inevitably, there will be winners and losers in any policy change, but the suspicion of many is that large corporations will stand to benefit most and that their gain will be societýs loss. The idea that the agreement will be made-to-measure for corporations has been strengthened by the perception that negotiations are conducted behind closed doors and shrouded in secrecy (more on this later).

TTIP and the pharmaceutical sector

The pharmaceutical sector is one of the most heavily regulated sectors there is and the need for alignment of regulatory practices in a global market was already recognized more than 25 years ago, with the launch of the International Conference on Harmonisation (ICH). Since its inception, the ICH has steadily driven a convergence of pharmaceutical regulations throughout the world. In recent years, the Food and Drug Administration (FDA) in the US and the European Medicines Agency (EMA) in Europe have been working together increasingly closely, with greater information sharing and numerous staff exchange programmes. Despite this convergence, many pharmaceutical companies are still frustrated by differences between the constituent regions of ICH and between the US and Europe in particular.

Paediatric medicines

For example, in the case of pediatric medicines, an approved paediatric development plan is now required on both sides of the Atlantic — a Pediatric Study Plan in the US and a Paediatric Investigation Plan in Europe. Not only are there differences in the structure of these two documents, but there are often differences in overall interpretation, with the result that companies may not be able to implement a single global paediatric development programme. The consequent duplication is not only costly for the companies but also potentially harmful to children as they may be unnecessarily exposed to investigational medicinal products. Duplication may also make it more difficult to conduct properly powered and scientifically meaningful trials if the patient pool is limited, particularly in indications where a number of new drugs are coming through (for example, multiple sclerosis) and competition for patients is already strong. In paediatric development, greater harmonisation would therefore seem desirable.

Scientific advice and GMP inspections

Harmonisation of scientific advice is also proposed. Currently, companies can go to either the FDA or the EMA for scientific advice, which although not binding, will usually shape the clinical development programme. Discrepant scientific advice may generate conflicts for the pharmaceutical companies. As for the paediatric plans, unification (or mutual recognition) of scientific advice would help eliminate some of the many uncertainties and duplication from drug development. The agencies too would be able to free up resources, which are often stretched. Duplication of effort may also be reduced by introducing mutual recognition of Good Manufacturing Practice inspections. Both these proposals seem like a natural extension of the climate of greater cooperation and sharing of information alluded to above.

Biosimilars

One final example of an area that may benefit from greater harmonisation is biosimilars. The patent protection (or data exclusively) of many blockbuster monoclonal antibodies has either expired or is due

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to expire soon. The coming years are therefore likely to see a huge growth in the number of biosimilars, with corresponding cost reductions. Given that everyone is on a steep learning curve with biosimilars, the agencies have been forced to develop the regulations rapidly and there are certain divergences between the US and Europe. Unlike generics, which often only require a relatively small (and cheap) bioequivalence study, demonstrating bioequivalence is more complex (and costly). Therefore, any divergences in the regulations are likely to magnify the uncertainties for the biosimilar companies and hinder the development of their products.

Wider impact on healthcare

As outlined above, although considerable progress has already been made in harmonisation of the regulations for drug development on both sides of the Atlantic, further convergence would seem potentially beneficial in some areas. So far, so good. As it stands, however, the TTIP would not just be limited to drug development but to the wider healthcare sector. This is where the main concerns start to appear. Clearly, healthcare provision is very different on each side of the Atlantic. European countries pride themselves on having universal healthcare systems, in stark contrast to the US, where private healthcare is the norm and any attempt to introduce universal access (e.g. Obamacare) is fiercely resisted. The greater commoditisation of healthcare in the US is also reflected by, for example, direct advertising of prescription medicines to consumers.

The main fear of many opponents to TTIP is that the agreement could give too much power to corporations to guide public health policy and impose a US-style approach to healthcare policy, in particular through the controversial Investor-to-State Dispute Settlement System (ISDS). This supposedly gives corporations the opportunity to take national governments to a tribunal of arbitration about legislation that leads to loss of profits. Examples of legislation that may impact corporate profits include banning logos on cigarette packets or campaigns to reduce soft-drink consumption by children. Although industry advocates claim that the ISDS would not provide a mechanism for companies to influence national health policy, some claim that the threat of legal action may lead to a 'regulatory chill', whereby governments are discouraged from passing health protection laws.

A transparent process?

Although TTIP could be beneficial for pharmaceutical companies and patients alike, it is hard to assess potential impacts if there is a lack of transparency in the process. Measures have been taken to improve transparency but these largely seem reactive (after high-profile leaks followed by protests) rather than proactive. For example, the TTIP texts have been made available to all Members of the European Parliament (MEPs) in a reading room (and it seems that material will also be made available to other 'selected individuals' outside Brussels). However, members are not allowed to remove restricted material from the reading room and they are not allowed to have specialist support to help them understand the complex technical material. No doubt, the TTIP negotiators have access to expert legal and technical opinion.

Proponents of the process are also at pains to point out that public consultations have been made. Again, these also appear reactive measures and anyway, without transparency, it is impossible to know the extent to which the opinions aired in these consultations are assimilated. Although the FDA and EMA are major stakeholders, the TTIP negotiations are hardly mentioned on their websites. Are they participating? And if so, why are they not communicating more about the negotiations? Overall, the sudden embrace of transparency feels rather superficial and the negotiators could do much more to reassure the public that the overall wellbeing of European citizens is being taken into account.

On balance...

In short, it is very difficult to determine whether TTIP will be a force for good or bad in the pharmaceutical sector. Certainly, greater regulatory harmonisation could benefit pharmaceutical companies and some of that benefit might trickle down to the end patient in terms of faster approvals and cheaper drugs (if the development costs are lower and these saving are passed on). Despite reassurances from participants in the process, the details of the deal are opaque, making a judgement on their impact difficult. And even if the full details were known outside the select circles involved in the negotiations, predictions of impacts would be difficult as the law of unintended consequences would likely apply in the face of the complexity of the issues. On perhaps the most contentious issue, the ISDS, it looks like the European Parliament will push back on its full implementation in the health sector. That is probably a good thing.

Reference

1. Francois J. Reducing Transatlantic Barriers to Trade and Investment: An Economic Assessment. March 2013. Centre for Economic Policy Research, London. Available from: http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc_150737.pdf.