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The Antidote

Taking a look at corporate inversions
and e-Health
September 2014



Welcome to the third edition of The Antidote

A summer of challenges...

Summer is nearly at an end and whilst corporate activity continued apace, including AbbVie acquiring Shire, Omega Pharma attracting acquisition interest, and GSK and Sanofi seeking to dispose of certain of their older drugs, some of you have been cooling off with the ALS Ice Bucket Challenge! This icy event not only brought attention to this rare disease, but highlighted that the drug development pipeline for ALS needed to be bolstered, and reminded us of the high level of costs associated with drug development, particularly if a drug fails. Let's see whether this innovative, albeit chilly, approach to raise awareness encourages more companies to look to drug development.

Costs remain a challenge that faces this industry sector and seem to have been rather prevalent this summer in relation to a number of high profile events. One of the most noticeable and recent being young Ashya King and his family's quest to seek proton beam therapy abroad. This treatment is seen as very expensive and the NHS only funds selected patients to be sent abroad for treatment. Such treatment should be available in the UK in 2018 for cancer patients.

Similarly, a new breast cancer treatment was rejected by NICE for routine use on the NHS as it was regarded as not affordable, and more recently the Scottish Medicines Consortium called it "extremely expensive". Such reactions are disappointing when improvements should be made to enable access to the latest drugs.

A further challenge facing the industry is one of ethics in relation to the largest, most severe and most complex outbreak of Ebola in West Africa with the death toll exceeding 1,500 and continuing to climb. Although there are a number of products in development, there are currently no medicines or vaccines approved for use in any country. However, in August, a committee of international experts convened by the WHO declared it to be ethical to offer unproven interventions with unknown efficacy and adverse effects as potential treatment for or prevention against Ebola. We will certainly continue to see what develops when the committee, including other experts, reconvenes to consider how to set the ethical criteria to prioritise the use of the experimental drugs and vaccines.

In all, an interesting summer, and one that certainly calls for the industry to reflect on its priorities.



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Upcoming events

We are planning a number of events to keep you up-to-date on key developments in the sector. We hope that you or your colleagues will be able to join us for these events.

Global Lifesciences Forum 2014: Amsterdam, Monday 10 November 10.00 – 17.00 CET

The Forum programme will focus on the future of the Lifesciences industry in and outside Europe. It will include presentations and insights from external industry experts and CMS lawyers and sector specialists.

Global Lifesciences webinar series

We have designed a series of hour-long webinars focusing on the key legal issues affecting the Lifesciences sector. The dates of the upcoming webinars are:

- 25 September** Public Procurement in Lifesciences
- 30 October** Personalised drugs
- 27 November** Distribution models in Lifesciences
- 18 December** Dawn raids

If you are interested in participating in the Global Lifesciences Forum or any of the above webinars, please contact **Samantha Jones** (samantha.jones@cms-cmck.com) for further details.

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Corporate inversions – rise and fall?

The last year has seen significant interest in potential “corporate inversions” by US headquartered groups. Corporate inversions essentially involve moving the headquarters of a group overseas. Groups headquartered in the US will pay US tax on both their US income and their income from foreign sources under the controlled foreign corporation (CFC) rules. Where the US tax rate is higher than the local tax rate, this means that US headquartered groups pay more tax than groups headquartered elsewhere.

Some recent examples of corporate inversions in the Pharma sector include AbbVie’s acquisition of Shire and Pfizer’s attempted acquisition of AstraZeneca. Whilst tax advantages are rumoured to be a driving factor in this phenomenon (and by some they have even been dubbed “tax inversions”), in reality are these tax advantages only a fortunate by product of a strategic acquisition?

Tax advantages are only achieved on a corporate inversion where a group has substantial profits from foreign sources, which is one reason why corporate inversions may be popular in the Pharma sector. Under current US law, a company that “merges” with an offshore counterpart can effectively move its headquarters abroad (notwithstanding that management and operations remain in the US), as long as at least 20 per cent. of the shares in the new parent company are held by the foreign company’s shareholders after the “merger”. Consequently, the overseas entity taken over has to be substantial (i.e. at least 20% of the size of the US entity) otherwise the US entity’s shareholders would suffer economic dilution. It follows that one of the other reasons why inversions are proving so popular in the Pharma sector is the current trend in that sector to use M&A in order to become more specialised and acquire assets that complement the buyer’s existing core products.

But is there really any mischief involved in these structures? It is common ground that artificially diverting profits overseas, in order to reduce tax liabilities, is an unacceptable form of tax planning and many jurisdictions have CFC rules designed to counteract this behaviour. This is not, however, what a corporate inversion is designed to achieve; a corporate inversion ensures that profits arising from genuine economic activities

undertaken offshore are taxed only in the local jurisdiction and in many jurisdictions (such as the UK) these profits would fall outside the CFC tax charge. Should a group really be faced with a higher tax bill on genuine offshore operations purely because its parent happens to be domiciled in the US; such a principle is difficult to reconcile with the EU tax principles of freedom of establishment and free movement of capital.

Irrespective of the moral rights and wrongs of corporate inversions, the negative press surrounding these structures has clearly had an impact on the market. For example, Walgreens has announced that its proposed acquisition of full control of Switzerland-based Alliance Boots will be effected without a corporate inversion, notwithstanding that such a transaction could potentially save the company billions of dollars in taxes. In addition, there is increasing pressure for US legislative changes that would make corporate inversions more difficult. Although strategic acquisitions will no doubt continue, it seems that US buyers will now think long and hard before structuring them in a tax efficient manner.

e-Health in Europe

e-Health is a relatively new “umbrella” term which describes medical services delivered via telecommunications technologies. Medical consultations being carried out via video link and remote monitoring of patients are just a number of e-Health initiatives already being rolled out in the UK. By harnessing technology, healthcare providers hope to maximise efficiency, reduce costs and improve access.

For businesses, the potential gains to be made by investing in e-Health are equally significant. The European market alone is estimated to be worth more than £40bn per annum.

Where’s the hitch?

Perceived legal issues have been blamed for impeding the roll-out of e-Health in Europe. However, these “barriers” may more accurately be described as hurdles which can be over-come through early planning.

Potential barriers

e-Health involves the transmission of patient health data. Under the European Data Protection regime, such data is “sensitive personal data” and use generally requires patients’ explicit consent. The current legal exemptions protect processing

by professional practitioners for the purposes of providing medical treatment. However, e-Health often involves data transmission to or between providers who are not health professionals and, as such, this exemption is inapplicable. It is therefore necessary to ensure that explicit consent to all processing for e-Health purposes is obtained in advance.

This need to consider consenting carefully is bolstered by the new draft European Data Protection Regulation. The Regulation champions the idea of “privacy by design”, requiring e-Health companies to build data protection compliance into their projects from the outset. Consents will need to be wide enough to accommodate all potential processing of the health data. Considering these issues early reduces the risk of subsequent compliance issues.

In addition, one of the primary aims of the Regulation is to reduce the legal burden by introducing a single regulator instead of the current 28 national regulators. This, coupled with the fact that health data in Europe is typically held within the public sector, gives us an advantage over jurisdictions where health data is less accessible.

The law also requires data controllers to ensure that data processors have adequate security in place to protect the data and generally restricts transfers of data outside the EEA. Technological advances, such as Cloud storage of personal data, also mean that the question of whom and where the data processor is, are complex. However, so long as businesses ensure that their legal position is protected through robust data processing agreements, security obligations should not be an insurmountable obstacle.

The rise of e-Health is also blurring the boundaries between historically distinct sectors: healthcare, telecommunications and consumer products. Each is heavily regulated and has its own regulatory regime and regulator. Ensuring compliance with relevant regulatory obligations requires foresight, diligence and detailed planning.

Summary

There are undoubtedly obstacles to the development of e-Health in Europe. However, the law need not sound the death knell. Businesses in Europe wishing to invest now to get a head-start should do so, but should maintain an “eyes open” approach to the legal hurdles that they may need to manoeuvre.

Our core Lifesciences group



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