Morgan Lewis

EUROPEAN LIFE SCIENCES REVIEW

Issue 2 – March 2016

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Welcome to the second issue of our EU life sciences alerter that covers some of the most critical developments in the pharmaceutical and medical technology sectors in the last month and is produced by our life sciences lawyers in London, Frankfurt, and Paris. If you have any questions on any of these issues, please contact Paul Ranson.

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Brexit-23 June 2016 Referendum

UK Prime Minister David Cameron has announced a referendum on whether Britain should remain in the EU to be held on Thursday 23 June 2016. As the 'in' and 'out' sides marshal their arguments, businesses and in particular the life sciences sector are giving thought to what would happen if the UK chose to leave the EU. Some critical potential issues could include the following:

Medical product regulation

If the UK were to remain in the EEA the regulatory framework for medicinal products and devices regimes would not change substantially. If the UK were to leave the EU and the EEA, the UK would have to negotiate mutual recognition agreements. Continued access to the EU centralised procedure administered by the European Medicines Agency (EMA) would be a critical factor. Currently the EMA can grant a single pan-EU marketing authorisation. If the UK fell outside the European regulatory framework, the UK would have to resume separate authorisations and inspections. The EMA would also have to relocate its UK headquarters to the potential detriment of drugs currently under regulatory review. For medical devices, issues would arise around the appropriateness of using non-UK notified bodies and the extent to which a CE-marking would afford free movement within the EU.

Intellectual property

With current patent registration and enforcement rules, an exit from the EU and/or the EEA could have limited impact. The effect would be greater were the Unitary Patent system in effect. The Unified Patent Court (UPC) is due to open its doors from the beginning of January 2017. UK lawmakers are unlikely to ratify the creation of a new UPC until after the UK public votes on whether the country should remain a member of the EU, the UK government has confirmed. An exit from the EU could substantially reverse parallel trade law, which is based on the European principle of free movement of goods.

Competition

The impact of the UK leaving the EU may be limited, as UK laws are already based substantively and procedurally on the EU competition law regime. However, potentially material issues could arise relative to:

- the applicability in the UK of European Commission (EC) decisions (e.g. in High Court Proceedings and proceeding before the CAT);
- the binding nature in the UK of General Court and Court of First Instance judgments;
- the extent to which the Competition and Markets Authority could come to a different finding from the EC.

Employment

While, overall, there would inevitably be some changes, the consequences are likely to be refinements rather than a radical overhaul, and would be subject to the political landscape at the time of an EU exit. It is perhaps telling that UK employment law is not one of the areas that the UK government has sought to renegotiate prior to the proposed referendum on the UK's continued membership in the EU.

Data Protection

The UK has enacted most of its domestic data protection laws, such as the Data Protection Act 1998, to implement European Directives. If the UK left the EU, existing domestic legislation would remain unless and until changed by the UK government. The application of the new EU Regulation (to become law in 2018) would also be in doubt.

Both the outcome and the consequences are unknown, but do contact us if specific risk management issues are of interest or concern, or visit our Brexit Resource Centre.

Safety

Falsified Medicines: Delegated Legislation on Safety Features

Starting in 2019, medicines in the EU will require unique identifiers and antitampering devices. The delegated legislation, published on 9 February 2016, is made under the Falsified Medicines Directive (2011/62/EU). The new legislation requires most medicines to have a unique identifier (a two-dimensional barcode) and an antitampering device on the packaging by 9 February 2019. The EMA and the EC have prepared an implementation plan, which can be found here.

Orphan Medicines

EMA Consultation on a New Notice

The EMA has recently consulted on replacing the 2003 Communication on Orphan Medicinal Products with a new notice. The consultation can be found here.

EU Orphan Medicinal Products Access

The EC has published its inventory of EU and member state incentives relating to orphan medicines. The report addresses the increased interest in the field and comments that member state reimbursement policies may impact the availability of orphan medicinal products, which could be an area of concern for the EU. The full report can be found here.

Clinical Research

Trial Data Transparency

The EMA has published an updated version of the external guidance on the implementation of the EMA policy on the publication of clinical data for medicinal products for human use. Please find the document here. The updated version of the guidance sheds further light on how EMA's Policy 0070 will work in practice. Under Policy 0070, the agency proactively publishes the clinical reports submitted as part of marketing-authorisation applications once the decisionmaking process is complete. Policy 0070 is composed of two phases: Phase 1 of Policy 0070 entered into force on 1 January 2015 and pertains to publication of clinical reports only. Phase 2, which will be implemented at a later stage, pertains to the publishing of individual patient data. The scope of the updated guidance only relates to Phase 1. In particular, the guidance covers the:

- procedural aspects related to the submission of clinical reports;
- asnonymisation of clinical reports for the purpose of publication; and
- identification and redaction of commercially confidential information in clinical reports.

Clinical Trials and Human Frailty

The EMA is consulting on 'Points to consider on frailty: Evaluation instruments for baseline characterisation of clinical trial populations' with a view to ensuring that older and frailer members of the population are properly represented in clinical trials. The consultation closes on 31 May 2016. Please see the draft guidance.

Promotion

ABPI Code

ABPI Code changes which come into effect 30 April 2016 cover in particular the following areas:

- Joint working with the NHS;
- Defining transfers of value in relation to disclosure of benefits to HCP; and
- Certification of meetings.

See the code changes here.

Related Product Areas

E-cigarettes

EU countries are preparing to tax e-cigarettes under the same regime as normal cigarettes, as member states agreed to take the first step by asking the EC to draft an 'appropriate legislative proposal' in 2017.

The ministers' draft conclusions said that e-cigarettes, as well as other 'novel' products, could cause 'inconsistencies and legal uncertainty' in the single market if they stayed exempt from the excise tax.

eHealth

The EC's DG CONNECT and the United States Department of Health and Human Services (HHS) have jointly updated a roadmap that guides European and US cooperation on eHealth. The consultation, which closed on 15 March 2016, sought comments on the roadmap. In December 2010, DG CONNECT and HHS signed a Memorandum of Understanding on Cooperation surrounding eHealth/Health IT and covered both developing internationally recognised standards and expanding the skilled Health IT workforce. This new third workstream, 'Transatlantic eHealth/Health IT Innovation Ecosystems', aims to optimise cooperation in relation to the other two work streams. See the consultation and background here.

Novel and Traditional Foods from Third Countries

Following the adoption in November 2015 of the EU Regulation on novel foods, the European Food Safety Authority (EFSA) has launched a public consultation (closing on 21 April 2016) on two draft guidance notes addressing the requirements for applications for authorisations of novel foods and traditional foods from third countries.

Market Access and Reimbursement

Cancer Drugs Fund New Process Proposal Consultation 2015

NHS England and the National Institute for Health and Care Excellence (NICE) have consulted on the role of the Cancer Drugs Fund (CDF) from April 2016. Under the current proposals, the fund will provide access to medicines while real-world data is collected to inform a decision on whether to adopt the drugs for routine commissioning. The new CDF will have a clear entry and exit criteria managed by NICE. It is proposed that NICE will make a draft recommendation prior to marketing authorisation. The consultation closed on 11 February 2016 and can be found here. It is proposed that the new scheme will go live on 1 July 2016. See the Cancer Drugs Fund paper here.

NICE Releases Report Outlining Their Involvement with the EAMS

NICE has released its report on the steps that it is taking to support the Early Access to Medicines Scheme. The report lists the stages of the Scheme and NICE's role at each stage, which includes working closely with the Medicines and Healthcare products' Regulatory Agency in order to enable quicker access to new treatments. The report can be found here.

PPRS Dispute Resolution Panel Decision on Combinations

Under the UK Pharmaceutical Price Regulation Scheme (PPRS) each participating company has to give a rebate to the Department of Health for its percentage for total NHS 'Sales covered by PPRS Payment' over the permitted NHS sales increase cap. Under the Scheme, 'Sales Covered by the PPRS Payment' expressly excludes 'Sales of new products'. These are defined as 'products introduced following the granting of *an EU or UK new active substance marketing authorisation* from the appropriate licensing body'. In a recent Dispute Regulation Panel hearing, Novartis argued that its Ultibro Breezhaler, a fixed dose combination of two established substances, should qualify as a new product. The Department of Health, however, argued that because the Ultibro does not contain any new active substances, but a combination of two known ones, it should not be considered a new product. In their conclusions, the panel found in favour of the department and that the product did not constitute a 'new active substance'. See the decision here.

Intellectual Property

EU Contracts Study of SPC System

The European Union Directorate General for Internal Market, Industry, Entrepreneurship and SMEs is seeking to conduct a study on the supplementary protection certificates (SPC) system. The aim of the study is to establish whether the current SPC rules 'need to be recalibrated given identified limitations'. The notice can be found here.

Commission Consultation on Intellectual Property Rights

The EC has published a public consultation on the evaluation and modernisation of the legal framework for the enforcement of intellectual property rights. The aim of the consultation is to evaluate if the Enforcement Directive is appropriate, specifically for online purposes. The consultation is open until **1 April 2016.** Please see the consultation documents.

Morgan Lewis – Update

Webinar on Data Privacy and Protection in Life Sciences: An EU and US perspective

Lawyers from our Washington DC, San Francisco, and London offices held a one-hour webinar to discuss the issues and recent changes arising from the evolving regulatory framework in both the United States and the EU. The recording can be heard here.

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