Morgan Lewis

EUROPEAN LIFE SCIENCES REVIEW

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Welcome to the first issue of our *EU Life Sciences Review*. It is produced by our life sciences lawyers in London, Brussels, Frankfurt, Moscow, and Paris and covers some of the most critical developments in the pharmaceutical and medical technology sectors in the last month. If you have any questions on any of these issues, please contact Paul Ranson.

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Data and Transparency

EU Court Declares EU/US Safe Harbor "Invalid" – What Now?

U.S. companies with European business will most likely mark 6 October 2015 as a dark day on their calendars. The highest EU court, the European Court of Justice (ECJ) in Luxembourg, declared a fifteen-year-old longstanding EU decision authorising a EU/US Safe Harbor "invalid." The judgment is not appealable. This is a serious issue for the entire industry. According to the European Commission, the United States is a country with "inadequate" data protection laws. The European Commission and the U.S. Department of Commerce, therefore, agreed in 2000 to a self-certification program for U.S. organisations that receive personal data from Europe operated by the U.S. Department of Commerce and enforced by the Federal Trade Commission. Thanks to the landmark ECJ decision, this Safe Harbor is now thrown into jeopardy. See the full article from Morgan Lewis here.

Data Protection Regulation Update

After nearly four years, European Parliament's Justice Committee formally adopted the text – of the new Data Protection Regulation on 17 December 2015. It is expected that the Regulation will become EU law in the early part of 2016, with a two year lead in period before it becomes enforced. The final wording of the document can be found here.

Regulatory

EMA Issues Draft Guidance on Post-authorisation Efficacy Studies

The EMA has consulted on draft scientific guidance to assist in the design of post-authorisation efficacy studies (PAES) and to deal with procedural queries. The use of PAES was recently extended from their historic use with medicines which were conditionally authorised or authorised under exceptional circumstances to cases where there may be continuing concern as to efficacy or understanding of the disease. The consultation closes on 31 January 2016. The guidelines may be found here.

EU Reaches Political Agreement on Novel Foods Legislation

Political agreement has been reached on the new Novel Foods Regulation. The Regulation sets up a centralised authorisation procedure through the European Food Safety Authority to streamline the introduction of novel food (foods not normally consumed before 1997) to the EU market. The new Regulation has to be formally adopted by the European Parliament and the Council. The new rules will come into force two years after the date of the new Regulation. The EU Commission statement can be found here.

Commission Review of Orphan Medicinal Products Guidance on Significant Benefit

The EU Commission issued a draft notice revising the 2003 Communication giving guidance to applicants under the Orphan Medicinal Products Regulation No 141/2000. In particular the draft suggests that the criteria for a finding of a significant benefit (a key criterion for orphan designation) will be more strictly construed. The draft notice can be found here.

Market Access and Reimbursement

NHS England to 2020

As a result of a combination of the Secretary of State for Health's obligation under the Health and Social Care Act 2012 to publish its objectives for NHS England for 2016/2017 and its requirement to set out its objectives to 2020, a consultation document sets out how the Government proposes to set the mandate to NHS England for this Parliament. The final mandate was to be subject to the outcome of the Government's 25 November 2015 Spending Review. The objectives include a commitment to continue the Cancer Drugs Fund. Consultation found here.

Accelerated Access Review (AAR) – the UK Government's Interim Report

The AAR team published its interim report in October 2015 having consulted through an engagement process of some 600 stakeholders and received 392 comments, 54 submissions and 97 survey responses. The somewhat high level interim report can be found here.

EU Council Conclusions on Personalised Medicine for Patients

The EU Council's conclusions on personalised medicines were adopted at the Council meeting on 7 December 2015. The conclusions state that the development of personalised medicine, individuals and health systems will face new challenges, including balancing its risks and benefits while also considering its ethical, financial, social and legal implications, particularly regarding pricing and reimbursement, data protection and public interest in processing personal data. The full conclusions can be found here.

Patents

Unitary Patent and National Patents and SPCs

In a recently published communication, the EU Commission addresses difficulties in the interrelationship between the Unitary Patent, national patents and supplementary protection certificates. Supplementary protection certificates ("SPCs") are granted by EU national patent authorities to compensate for the loss of effective patent term whilst seeking marketing authorisations. The proposals for a new unitary patent covering the EU have led to debate within the EU Commission as to how it would best co-exist with the existing SPC regime. The consensus seems to be that SPCs should be available based on Unitary Patents, the "basic patents", but continue to be granted on a national basis but no final determination has yet surfaced.

EU Commission's Latest Report on Patent Settlements Covering 2014

The Commission's 6th Report on the Monitoring of Patent Settlements covering the period January 2014 - December 2014 was published on 2 December 2015. The Commission has, since 2009, been investigating patent settlements in the pharmaceutical industry particularly where they might lead to a delay of generic entry in return for a payment by the originator company to the generic company. The full report can be found here.

Environmental

No More Flushing: EPA Releases New Rules for Managing Pharmaceutical Waste

On 25 September 2015, the Environmental Protection Agency formally published proposed regulations that will, if finalised, change the way that hazardous waste pharmaceuticals are managed at health care facilities (including pharmacies) and at pharmaceutical reverse distributors. Full article here.

Tax Issues

UK to Modify Patent Box in Line with OECD Recommendations

The UK has recently announced that it will amend the existing 'Patent Box' preferential tax rate for innovation so that they comply with OECD recommendations. The Consultation may be found here.

Morgan Lewis – News

10 Feb: Data Privacy and Protection in Life Sciences an EU and US Perspective

Data transfer is a crucial issue for companies that work in the life sciences sector and is a highly regulated and ever-changing regime. Typical personal data categories transferred from organisations to third parties include clinical trial data, data relating to unlicensed/compassionate use, health technology assessment data, transfers of value records for transparency reports, patient information enquiries for marketed products, and other patient and employee personal data.

Join us for a one-hour webinar to review the recent changes and learn how to navigate this evolving regulatory framework. Register here.

Recording: Medicines Pricing and Reimbursement Demonstrating Value and Sharing Risk in the EU and United States

Lawyers from our Washington and London offices held a one-hour webinar to discuss the issues and challenges arising from the growing need in both the EU and the US for producers to demonstrate value and share risk. The recording can be heard here.

Morgan Lewis – Spotlight

Paul Ranson

Paul Ranson focuses on the regulatory and commercial needs of the pharmaceutical, biotechnology, and medical devices sectors. He joins Morgan Lewis with over 30 years of experience in the life sciences industry, including in-house roles with Merck (US) and Lilly and partnership at another major international law firm. Paul's current activities include acting as general counsel to a large respiratory drug-delivery development company. In the past he has worked extensively with some of the largest international life sciences companies. Paul's regulatory expertise covers both marketing authorisation-related matters and market access, pricing, and reimbursement issues. His commercial work is concentrated on transactions with a high degree of industry specificity including collaborations and outsourcing transactions. Paul further strengthens our London office's increasing presence in the European life sciences market. His arrival builds on the recent expansion of our European life sciences practices; enhancing our ability to serve clients in Europe and complementing the significant cross-border services we provide from our US and European offices.

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